NOVADEL PHARMA INC
Form 10-Q
May 17, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2010

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____ .

COMMISSION FILE NO. 001-32177

NOVADEL PHARMA INC.
(Exact name of registrant as specified in its charter)

Delaware	22-2407152
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1200 ROUTE 22 EAST, SUITE 2000, BRIDGEWATER, NEW JERSEY 08807
(Address of principal executive offices) (Zip Code)

(908) 203-4640
Registrant’s telephone number, including area code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if

any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of May 1, 2010, the issuer had 98,383,000 shares of common stock, $.001 par value, outstanding.

NOVADEL PHARMA INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2010

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SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This Quarterly Report on Form 10-Q includes “forward-looking statements”, including statements regarding NovaDel Pharma Inc.’s (the “Company,” “we,” “us” or “NovaDel”) expectations, beliefs, intentions or strategies for the future and the Company’s internal controls and procedures and outstanding financial reporting obligations and other accounting issues. The Company intends that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect the Company’s views as of the date they are made with respect to future events and financial performance. In particular, the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section in Part I, Item 2 of this Quarterly Report on Form 10-Q includes forward-looking statements that reflect the Company’s current views with respect to future events and financial performance. The Company uses words such as “expect,” “anticipate,” “believe,” “intend” and similar expressions to identify forward-looking statements. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. A number of important risks and uncertainties could, individually or in the aggregate, cause actual results to differ materially from those expressed or implied in any forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type the Company is developing (independently and through collaborative arrangements); the inherent risks and uncertainties in completing the pilot pharmacokinetic feasibility studies being conducted by the Company; possible changes in the Company’s financial condition; the progress of the Company’s research and development; inadequate supplies of drug substance and drug product; timely obtaining sufficient patient enrollment in the Company’s clinical trials; the impact of development of competing therapies and/or technologies by other companies; the Company’s ability to obtain additional required financing to fund its research programs and its ongoing business operations; the Company’s ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with the Company; the progress of the U.S. Food and Drug Administration, or FDA, approvals in connection with the conduct of the Company’s clinical trials and the marketing of the Company’s products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; acceptance for filing by the FDA does not mean that the New Drug Application, or NDA, has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted; the risks related to the Company’s internal controls and procedures; and the risks identified under the section entitled “Risk Factors” included as Item 1A in Part II of this Quarterly Report on Form 10-Q and other reports, including this report and other filings filed with the Securities and Exchange Commission from time to time.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NOVADEL PHARMA INC.
CONDENSED BALANCE SHEETS
AS OF MARCH 31, 2010 (UNAUDITED) AND DECEMBER 31, 2009

	March 31, 2010 (unaudited)	December 31, 2009 (Note 2)
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 3,647,000	$ 2,663,000
Note receivable related to financing	800,000	—
Prepaid expenses and other current assets	268,000	1,430,000
Total Current Assets	4,715,000	4,093,000
Property and equipment, net	298,000	324,000
Other assets	19,000	36,000
TOTAL ASSETS	$ 5,032,000	$ 4,453,000
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current Liabilities:		
Accounts payable	$ 222,000	$ 195,000
Accrued expenses and other current liabilities	157,000	117,000
Accrued financing costs	125,000	—
Derivative liability	913,000	—
Current portion of deferred revenue	4,266,000	4,266,000
Current portion of capital lease obligations	10,000	10,000
Total Current Liabilities	5,693,000	4,588,000
Non-current portion of deferred revenue	4,136,000	4,202,000
Non-current portion of capital lease obligations	2,000	4,000
Total Liabilities	9,831,000	8,794,000
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIENCY		
Preferred stock, $.001 par value:		
Authorized 1,000,000 shares, none issued	—	—
Common stock, $.001 par value:		
Authorized 200,000,000 shares, Issued 98,383,458 and 88,343,457 shares at March 31, 2010 and December 31, 2009, respectively	99,000	89,000
Additional paid-in capital	79,166,000	78,342,000
Accumulated deficit	(84,058,000)	(82,766,000)

Less: treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
Total Stockholders' Deficiency	(4,799,000)	(4,341,000)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	$ 5,032,000	$ 4,453,000

See accompanying notes to condensed financial statements.

NOVADEL PHARMA INC.
CONDENSED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED
MARCH 31, 2010 AND 2009
(UNAUDITED)

	Three Months Ended	
	March 31, 2010	March 31, 2009
License Fees and Milestone Fees Earned	$ 129,000	$ 66,000
Research and Development Expenses	447,000	826,000
Consulting, Selling, General and Administrative Expenses	974,000	1,258,000
Total Expenses	1,421,000	2,084,000
Loss From Operations	(1,292,000)	(2,018,000)
Other Income	—	360,000
Interest (Expense), net	—	(481,000)
Net Loss	$ (1,292,000)	$ (2,139,000)
Basic and Diluted Loss Per Common Share	$ (0.01)	$ (0.04)
Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Common Share	88,372,000	59,892,000

See accompanying notes to condensed financial statements.

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NOVADEL PHARMA INC.
CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIENCY
FOR THE THREE MONTHS ENDED MARCH 31, 2010
(UNAUDITED)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Total Stockholders' Deficiency
	Shares	Amount				
BALANCE, December 31, 2009	88,343,457	$89,000	$78,342,000	$(82,766,000)	$(6,000)	$ (4,341,000)
Share-based compensation expense			205,000			205,000
Restricted stock cancelled	(60,000)					
Issuance of Common Stock	10,100,001	10,000	619,000			629,000
Net loss				(1,292,000)		(1,292,000)
BALANCE, March 31, 2010	98,383,458	$99,000	$79,166,000	$(84,058,000)	$(6,000)	$ (4,799,000)

See accompanying notes to condensed financial statements.

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NOVADEL PHARMA INC.
CONDENSED STATEMENTS OF CASH FLOWS
FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009
(UNAUDITED)

	Three Months Ended	
	March 31, 2010	March 31, 2009
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (1,292,000)	$ (2,139,000)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Share-based compensation expense	205,000	149,000
Expiration of warrants	—	(360,000)
Amortization of debt discount and deferred financing fees	—	367,000
Depreciation and amortization	26,000	106,000
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,162,000	368,000
Accounts payable	27,000	(94,000)
Accrued expenses and other current liabilities	40,000	94,000
Deferred revenue	(66,000)	(66,000)
Net cash provided by (used in) operating activities	102,000	(1,575,000)
CASH FLOWS FROM INVESTING ACTIVITIES		
Return of lease deposits	17,000	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net Proceeds from issuance of common stock and warrants	867,000	
Payments of capital lease obligations	(2,000)	(37,000)
Net cash provided by (used in) financing activities	865,000	(37,000)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	984,000	(1,612,000)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	2,663,000	4,328,000
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 3,647,000	$ 2,716,000
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Derivative Liability	$ 913,000	—
Note Receivable related to Financing	$ 800,000	—
Accrued Financing Costs	$ 125,000	—

See accompanying notes to condensed financial statements.

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NOVADEL PHARMA INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

NOTE 1 - NATURE OF THE BUSINESS

NovaDel Pharma Inc. (the "Company") is a specialty pharmaceutical company developing oral spray formulations for a broad range of marketed drugs. The Company's proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly reduced first pass liver metabolism, which may result in lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and adherence. The Company's oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products, with the most advanced oral spray candidates targeting angina, nausea, insomnia, migraine headaches and disorders of the central nervous system.

NOTE 2 – BASIS OF PRESENTATION AND LIQUIDITY

The balance sheet at December 31, 2009 has been derived from the audited balance sheet contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009 and is presented for comparative purposes. All other financial statements are unaudited. The condensed financial statements are presented on the basis of accounting principles generally accepted in the United States of America for interim financial statements. However, certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been omitted in accordance with the published rules and regulations of the Securities and Exchange Commission. The condensed financial statements in this report should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect reported loss, financial position and various disclosures. Actual results could differ from those estimates. In the opinion of management, all adjustments, which include only normal recurring adjustments, necessary to present fairly the financial position, results of operations and cash flows for all periods presented, have been made in the interim financial statements. Results of operations for interim periods are not necessarily indicative of the operating results to be expected for a full fiscal year.

The Company has reported a net loss of $1,292,000 and $2,139,000 and cash flows provided by (used in) operating activities of $102,000 and $(1,575,000) for the three months ended March 31, 2010 and 2009, respectively. As of March 31, 2010, the Company had negative working capital of $978,000 and cash and cash equivalents of $3,647,000. Until and unless the Company's operations generate significant revenues and cash flow, the Company will attempt to continue to fund operations from cash on hand and through the sources of capital described below. The Company's long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of the Company's equity or debt securities or bridge loans to the Company from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. The Company can give no assurances that any additional capital that it is able to obtain will be sufficient to meet its needs, or on terms favorable to it.

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Since the fourth quarter 2007 and continuing through the first quarter 2010, the Company has significantly reduced clinical development activities on its product candidate pipeline, such that the Company has limited its expenditures primarily to those required to support its two approved products NitroMist™ and Zolpimist™ and minor expenditures to support formulation development activities for certain other products, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, the Company requires capital to sustain its existing organization until such time as clinical activities can be resumed. The Company received $1,055,000 in gross proceeds for common stock purchased by Seaside 88, LP during the year ended December 31, 2009. During the fourth quarter of 2009, the Company also entered into licensing and distribution agreements with ECR Pharmaceuticals Company, Inc. and Mist Acquisition, LLC, as a result of which it received non-refundable license fees of $4,000,000. On March 31, 2010, the Company announced it would receive approximately $1.5 million in gross proceeds from its registered direct offering (the "Offering") of 9,100,001 shares of common stock, par value $0.001 per share (the "Common Shares"), at a price of $0.165 per share. The investors received five-year warrants (the "Series A Warrants") to purchase 4,550,001 shares of common stock with an exercise price of $0.25 per share and six-month warrants (the "Series B Warrants," together with the Common Shares and the Series A Warrants, the "Securities") to purchase 3,033,334 shares of common stock at an exercise price of $0.25 per share. As of March 31, 2010, the Company recorded net proceeds of $551,000 and a note receivable of $800,000 which was subsequently received on April 15, 2010, relating to the Offering. The exercise price of the Series A and Series B Warrants are subject to adjustment as provided by such warrants. The Offering closed on March 31, 2010 and the Company sold the Securities pursuant to an effective registration statement.

The Company will seek to raise additional capital in 2010 to fund its operations and future development activities through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or, if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us. If we are unable to raise additional capital, and we do not use our existing working capital to fund our development plans, we will have sufficient cash on hand to fund operating costs through the fourth quarter 2010.

Our audited financial statements for the year ended December 31, 2009, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in the Company.

On May 14, 2008, we received notice from the NYSE Amex LLC (formally known as the American Stock Exchange) indicating that we are not in compliance with certain of the NYSE Amex LLC continued listing standards. Specifically, the NYSE Amex LLC has notified us that we are not in compliance with Section 1003(a)(iii) of the NYSE Amex LLC Company Guide with stockholders' equity of less than $6,000,000 and losses from continuing operations and net losses in our five most recent fiscal years, and Section 1003(a)(iv) of the NYSE Amex LLC Company Guide in that we have sustained losses which are so substantial in relation to our overall operations or our existing financial resources, or our financial condition has become so impaired that it appears questionable, in the opinion of the NYSE Amex LLC, as to whether we will be able to continue operations and/or meet our obligations as they mature. On December 2, 2009, we formally notified NYSE Amex LLC of our intent to voluntarily withdraw our listing and registration. On December 14, 2009, we filed Form 25 voluntarily withdrawing our listing and registration

from NYSE Amex LLC (“AMEX”). The final day of trading on AMEX was December 23, 2009. On December 24, 2009, we announced that our common stock will begin trading on the Over-the-Counter Bulletin Board (“OTCBB”) under its new ticker symbol on OTCBB as NVDL.OB.

NOTE 3 – AMORTIZATION OF DEBT DISCOUNT AND DEFERRED FINANCING FEES

For the three months ended March 31, 2009, the Company has recorded additional interest expense of $367,000 related to the amortization of debt discount and deferred financing costs. On December 31, 2009, the related debt was converted to common stock.

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NOTE 4 – COMMON STOCK ISSUANCE

On July 17, 2009, the Company entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP would purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than or equal to the stated floor price of $0.25 per share. The Company received net proceeds of $1,183,000 thru March 31, 2010 of which $191,000 was received for 1,000,000 shares during the three months ended March 31, 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP.

On March 31, 2010, the Company announced it would receive approximately $1.5 million in gross proceeds from its registered direct offering (the "Offering") of 9,100,001 shares of common stock, par value $0.001 per share (the "Common Shares"), at a price of $0.165 per share. The investors received five-year warrants (the "Series A Warrants") to purchase 4,550,001 shares of common stock with an exercise price of $0.25 per share and six-month warrants (the "Series B Warrants," together with the Common Shares and the Series A Warrants, the "Securities") to purchase 3,033,334 shares of common stock at an exercise price of $0.25 per share. As of March 31, 2010, the Company recorded net proceeds of $551,000 and a note receivable of $800,000 which cash proceeds were subsequently received on April 15, 2010, relating to the Offering. The exercise price of the Series A and Series B Warrants are subject to adjustment as provided by such warrants. The Offering closed on March 31, 2010 and the Company sold the Securities pursuant to an effective registration statement.

NOTE 5 – DERIVATIVE LIABILITY

Accounting Standard Codification "ASC" 815 – Derivatives and Hedging provides guidance on determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in the pronouncement on accounting for derivatives. These requirements can affect the accounting for warrants and many convertible instruments with provisions that protect holders from a decline in the stock price (or "down-round" provisions). Warrants with such provisions will no longer be recorded in equity. Down-round provisions reduce the exercise price of a warrant or convertible instrument if a company either issues equity shares for a price that is lower than the exercise price of those instruments or issues new warrants or convertible instruments that have a lower exercise price. We evaluated whether warrants to acquire stock of the Company contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price under the respective warrant agreements. We determined that the warrants issued in connection with the March 31, 2010 sale of the Company's common stock contained such provisions, thereby concluding they were not indexed to the Company's own stock and were treated as derivative liabilities.

The Company estimated the fair value of the warrants as of March 31, 2010 to be $913,000 by recording a corresponding reduction in additional paid-in capital. Two classes of warrants were issued; Series A warrants totaling 4,550,001 with a term of 5 years and Series B warrants totaling 3,033,334 with a term of 0.5 years. The exercise price for the Series A and B warrants are $0.25. In accordance with this pronouncement, the Company estimated the fair value of the related warrants to purchase shares of the Company's common stock at $755,992 and $156,719, respectively. As of March 31, 2010, the fair values of these derivatives totaled $913,000 and are recorded in the accompanying condensed balance sheet as of March 31, 2010 as derivative liability.

The Company utilizes the Black-Scholes option pricing model to estimate the fair value of these derivative instruments. The Company considers them to be Level 2 type instruments in accordance with ASC 820-10 - Fair Value Measurements and Disclosures as the inputs used to estimate their value are observable either directly or indirectly. The risk-free interest rate assumptions were based upon the observed interest rates appropriate for the

remaining contractual term of the instruments. The expected volatility assumptions were based upon the historical volatility of the Company's common stock. The expected dividend yield was assumed to be zero as the Company has not paid any dividends since its inception and does not anticipate paying dividends in the foreseeable future. The expected term assumptions were based upon the remaining contractual terms of these instruments.

	Series A Warrants	Series B Warrants
Discount Rate	2.55 %	0.24%
Volatility	140 %	131%
Expected Term	5 years	0.5 years
Dividend Yield	0 %	0%

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NOTE 6 – CASH EQUIVALENTS

Cash equivalents consist of money market instruments with maturities of three months or less when purchased. At times, such investments may be in excess of the Federal Deposit Insurance Corporation ("FDIC") insurance limit. Generally, these deposits may be redeemed and are maintained with high quality financial institutions, therefore reducing credit risk.

NOTE 7 – LOSS PER SHARE

The Company's basic loss per share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted loss per common share is the same as basic loss per common share, since potentially dilutive securities from the assumed exercise of all outstanding options and warrants, and from the conversion of the convertible notes, would have an anti-dilutive effect because the Company incurred a net loss during each period presented. As of March 31, 2010 and 2009, there were 35.9 million and 44.0 million common shares, respectively, issuable upon exercise of options and warrants, the vesting of non-vested restricted common stock, and the conversion of the convertible notes, which were excluded from the diluted loss per share computation.

NOTE 8 – STOCK-BASED COMPENSATION

At March 31, 2010, the Company had two plans which allow for the issuance of stock options and other awards: the 1998 Stock Option Plan, as amended, and the 2006 Equity Incentive Plan, as amended (the "Plans"). On January 17, 2006, the stockholders of the Company, upon the recommendation of the Board of Directors of the Company, approved the NovaDel Pharma Inc. 2006 Equity Incentive Plan (the "2006 Plan"). The 2006 Plan authorizes the grant of several types of stock-based awards, including stock options, stock appreciation rights and stock (including restricted stock). The number of shares of common stock originally reserved for issuance under the 2006 Plan was 6 million shares. These Plans are administered by the Compensation Committee of the Board of Directors. Incentive Stock Options ("ISOs") may be granted to employees and officers of the Company and non-qualified options may be granted to consultants, directors, employees and officers of the Company. Options to purchase the Company's common stock may not be granted at a price less than the fair market value of the common stock at the date of grant and will expire not more than 10 years from the date of grant. Vesting is determined by the Compensation Committee of the Board of Directors. ISOs granted to a 10% or more stockholder may not be for less than 110% of fair market value or for a term of more than five years. As of March 31, 2010, there were approximately 1.1 million shares available for issuance under the Plans.

The Company calculates the fair value of stock based compensation using the Black-Scholes method. Stock-based compensation costs are recorded as earned for all unvested stock options outstanding. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date.

Information with respect to stock option activity for the three months ended March 31, 2010 is as follows:

Options	Shares (000)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (Years)	Aggregate Intrinsic Value ($000)
Outstanding at December 31, 2009	8,279	$ .81		
Grants				

Exercises				
Forfeitures	(210)	0.88		
Outstanding at March 31, 2010	8,069	0.81	3.9	—
Vested and expected to vest at March 31, 2010	7,904	0.82	3.8	—
Exercisable at March 31, 2010	4,760	1.14	3.2	—

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The Company recorded share-based compensation expense of approximately $205,000 for the three months ended March 31, 2010 and $149,000 for the three months ended March 31, 2009. All such amounts are included in the Company's net loss for each period. Share-based compensation expense for the current quarter increased due to additional stock options granted during the fourth quarter 2009.

On February 6, 2008, the Company's Board of Directors, upon the recommendation of the Compensation Committee, approved grants of 750,000 shares of restricted common stock to the executive officers of the Company and an additional 350,000 shares of restricted stock to other employees of the Company. The restricted stock was awarded from the Company's 1998 Stock Option Plan. The restrictions on the restricted stock shall lapse over a three-year period.

A summary of the status of the Company's non-vested restricted common stock as of March 31, 2010 and changes during the three months ended March 31, 2010 is presented below:

Non-Vested Restricted Common Stock	Shares (000)	Weighted Average Grant-Date Fair Value
January 1, 2010	525	$ 0.47
Cancellations	(60)	$ 0.47
March 31, 2010	465	$ 0.47

As of March 31, 2010, unamortized share-based compensation expense of $664,700 remains to be recognized, which is comprised of $394,600 related to non-performance based stock options to be recognized over a weighted average period of 1.5 years, $104,500 related to restricted stock to be recognized over a weighted average period of 1.1 years, and $165,600 related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

The Company used the following weighted average assumptions in determining fair value under the Black-Scholes model for grants of all stock options in the respective periods:

	Three Months Ended	
	March 31, 2010	March 31, 2009
Expected volatility	—	85%
Dividend yield	—	0%
Expected term (years)	—	3.06
Risk-free interest rate	—	1.7%

Expected volatility is based on historical volatility of the Company's common stock. The expected term of options is estimated based on the average of the vesting period and contractual term of the option. The risk-free rate is based on U.S. Treasury yields for securities in effect at the time of grant with terms approximating the expected term until exercise of the option. In addition, the fair value of stock options granted is recognized as expense over the service period, net of estimated forfeitures. The Company is utilizing a 5% forfeiture rate, which it believes is a reasonable assumption to estimate forfeitures. However, the estimation of forfeitures requires significant judgment, and to the extent actual results or updated estimates differ from its current estimates, the effects of such resulting adjustment will be recorded in the period estimates are revised. The Company did not grant any stock options during the three months ended March 31, 2010. Stock options of 2.2 million were granted to employees and directors, including 800,000 performance-based stock options, during the three months ended March 31, 2009. The weighted average grant date fair value of options granted was $0.34 during the three months ended March 31, 2009.

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NOTE 9 - RELATED PARTY TRANSACTIONS AND LICENSE AND DEVELOPMENT AGREEMENTS

Related Party Transactions

In September 2006, the Company's Board of Directors appointed Steven B. Ratoff as Chairman of the Board. In connection with Mr. Ratoff's appointment as Chairman of the Board, the Board entered into a consulting arrangement to compensate Mr. Ratoff for his efforts. This arrangement was on a month-to-month basis and has compensated Mr. Ratoff at a rate of between $10,000 and $17,500 per month depending upon the amount of his involvement at the Company. In January 2010, the Company's Board of Directors appointed Steven B. Ratoff as President and Chief Executive Officer effective January 1, 2010. Mr. Ratoff will continue to serve as Interim Chief Financial Officer. Additionally, Mr. Ratoff is a private investor in, and since December 2004 has served as a venture partner with, ProQuest Investments. As of March 31, 2010, ProQuest Investments owns 34.4 million shares of Company stock which includes 4.8 million shares acquired in conjunction with the recent Offering of 9.1 million shares of common stock. As payment for the acquired shares, ProQuest Investments issued a promissory note for $800,000 for which the Company received the cash payment on April 15, 2010.

License and Development Agreements

Mist Acquisition, LLC. On October 27, 2009, we and privately-held Mist Acquisition, LLC, entered into a licensing agreement to manufacture and commercialize the NitroMist® lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris, in the United States, Canada and Mexico. Under terms of the agreement, Mist paid us a $1,000,000 licensing fee upon execution of the agreement, and will pay milestone payments totaling an additional $1,000,000 over twelve months if certain conditions are met, and ongoing performance payments of seventeen percent (17%) of net sales, subject to the terms of the agreement.

Through a separate license agreement with Mist, Akrimax Pharmaceuticals, LLC will receive the exclusive right to manufacture, distribute, market and sell NitroMist® in North America. NitroMist® provides acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. The lingual spray form of the drug is conveniently administered and is rapidly absorbed into the bloodstream via the oral mucosa, providing patients a fast and tolerable treatment option for the prevention or relief of pain associated with such attacks.

ECR Pharmaceuticals Company, Inc. On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. (a wholly-owned subsidiary of Hi-Tech Pharmacal Co., Inc.) to commercialize and manufacture ZolpiMist™ in the United States and Canada. ZolpiMist™ is the Company's oral spray formulation of zolpidem tartrate approved by the FDA in December of 2008.

Under the terms of the agreement, we received a $3,000,000 licensing fee from ECR upon execution of the agreement. ECR will assume responsibility for manufacturing and marketing the product in the United States and Canada. In addition, ECR will pay royalties of up to 15% on net sales of ZolpiMist™ as well as an additional milestone payment if sales reach a specified level.

BioAlliance. On May 19, 2008, the Company and BioAlliance Pharma SA or BioAlliance, entered into an agreement where BioAlliance acquired the European rights for NovaDel's Ondansetron oral spray. Under the terms of the agreement, BioAlliance paid NovaDel a license fee of $3,000,000 upon closing. The Company is eligible for additional milestone payments totaling approximately $24 million (an approval milestone of $5,000,000 and sales-related milestone payments of approximately $19 million) as well as a royalty on net sales. BioAlliance and the Company anticipate collaborating in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. The Company will be responsible for supplying the product. The upfront payment has been included in deferred revenue and is being

recognized in income over the term of the agreement (nineteen and one half-years). During each of the three months ended March 31, 2010 and 2009, the Company recognized $38,462 of income related to this contract.

Hana Biosciences, Inc./Par Pharmaceutical, Inc. In October 2004, the Company entered into a license and development agreement pursuant to which the Company granted to Hana Biosciences, Inc. (“Hana Biosciences”) an exclusive license to develop and market Zensana™, the Company’s oral spray version of Ondansetron in the U.S. and Canada. Pursuant to the terms of the agreement, in exchange for $1,000,000, Hana Biosciences purchased 400,000 shares of the Company’s common stock at a per share price equal to $2.50, a premium of $0.91 per share or $364,000 over the then market value of the Company’s common stock. The Company accounted for this premium as deferred revenue related to the license. In connection with the agreement, Hana Biosciences issued to the Company $500,000 worth of common stock of Hana Biosciences (73,121 shares based on a market value of $6.84 per share).

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The fair value of the common stock received from Hana Biosciences was included in deferred revenue and was being recognized over the 20-year term of the agreement.

In July 2007, the Company, entered into a Product Development and Commercialization Sublicense Agreement (the "Sublicense Agreement") with Hana Biosciences and Par Pharmaceutical, Inc. ("Par"), pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™. In connection therewith, the Company and Hana Biosciences amended and restated their existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana™ (the "Amended and Restated License Agreement") to coordinate certain of the terms of the Sublicense Agreement. Under the terms of the Sublicense Agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada. The Company retains its rights to Zensana™ outside of the United States and Canada.

In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to pay reduced royalty rates to the Company until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and the Company agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock, with a fair value of $140,000, that had been acquired by the Company in connection with execution of the original License Agreement. During 2007 the Company wrote off the entire investment in common stock. The Company may receive additional milestone payments and royalties over the term of the agreement.

Velcera. In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to the Company's propriety oral spray technology in animals. In September 2004, the Company received $1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The upfront payment has been included in deferred revenue and is being recognized in income over the 20-year term of the agreement. In addition, the Company received an equity stake of 529,500 shares of common stock in Velcera which did not have a material value. Such investment continues to be carried at its cost basis of $0 as of March 31, 2010. In February 2007, Velcera merged with Denali Sciences, Inc., a publicly reporting Delaware corporation. In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health. The agreement called for Novartis Animal Health to develop, register and commercialize a novel canine product utilizing Velcera's Promist™ platform, which is based on its patented oral spray technology. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. In November 2007, the common stock of the merged companies began trading on the OTC bulletin board. On March 5, 2008, Velcera announced that it had received notice from Novartis Animal Health that it was terminating the agreement, without cause. On October 17, 2008, Velcera announced that it had filed a Form 15 with the SEC, as a result of which Velcera's obligation to file reports with the SEC has terminated. On August 24, 2009, the Company issued a press release to announce that it received a milestone payment of approximately $150,000 from Velcera, Inc. relating to its license agreement. On March 5, 2010, the Company received another milestone payment of $62,500. These milestone payments resulted from Velcera's global licensing agreement for the first canine pain management product delivered in a transmucosal mist form.

Manhattan Pharmaceuticals, Inc. In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to the Company's proprietary oral spray technology to deliver propofol for pre-procedural sedation. The terms of the agreement call for certain license, milestone and other payments, the first $125,000 of which was received in June 2003. In November 2003, the Company received $375,000 from Manhattan Pharmaceuticals for license fees. The Company has included these license fees in deferred revenue and is recognizing these license fees over the 20-year term of the license. In July 2007, Manhattan Pharmaceuticals, the Company's partner for its propofol oral spray product candidate, announced that as part of its change in strategic focus it intends to pursue appropriate sub-licensing opportunities for this product candidate.

INyX/DPT Laboratories. On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX whereby INyX manufactures and supplies NitroMist™. For a five-year period that began November 18, 2004, INyX was to be the exclusive provider of the nitroglycerin lingual spray to the Company substantially worldwide. Pursuant to the terms and conditions of the agreement, it would be INyX's responsibility to manufacture, package and supply NitroMist™ in such territories. Thereafter, INyX would have a non-exclusive right to manufacture such spray for an additional five years. In July 2007, INyX announced it filed for protection under the Chapter 11 bankruptcy laws. The Company was informed by the trustees for INyX in June 2008 that the facility in Puerto Rico where manufacturing operations for NitroMist™ were conducted would be ceasing operations as of the end of July 2008. As a result, the Company selected an alternative contract manufacturing company, DPT Laboratories Inc ("DPT"), and has transferred manufacturing operations for NitroMist™ to DPT.

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NOTE 10 – OTHER INCOME

FASB ASC 815-40-15 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock for purposes of determining the appropriate accounting treatment. ASC 815-40-15 was effective as of the beginning of our 2009 fiscal year. The adoption resulted in an adjustment to opening accumulated deficit for fiscal year 2009 in the amount of $360,000 to account for the reclassification of the fair value of certain outstanding warrants from stockholders' deficiency to liability. The warrants affected by the adoption expired during the first quarter of 2009 and, as a result, the fair value of the warrant liability was reduced to zero as of the end of the reporting period.

NOTE 11– NEW ACCOUNTING PRONOUNCEMENTS

In April 2010, an accounting standard update was issued to provide guidance on defining a milestone and determining when it is appropriate to apply the milestone method of revenue recognition for research and development transactions. Vendors can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period the milestone is achieved if the milestone meets all the criteria stated in the guidance to be considered substantive and must be considered substantive in its entirety. The amendments in this update will be effective prospectively for milestones achieved in fiscal years and interim periods beginning on or after June 15, 2010, with early adoption permitted.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. The discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in Part II; Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward looking statements.

GENERAL

NovaDel Pharma Inc. is a specialty pharmaceutical company developing oral spray formulations for a broad range of marketed drugs. Our proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and compliance. Our oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products. Our most advanced oral spray candidates target angina, nausea, insomnia, migraine headaches and disorders of the central nervous system. We plan to develop these and other products independently and through collaborative arrangements with pharmaceutical and biotechnology companies. Currently, we have nine patents which have been issued in the U.S. and 52 patents which have been issued outside of the U.S. Additionally, we have over 60 patents pending around the world. We look for drug compounds that are off patent or are coming off patent in the near future, and we formulate these compounds in conjunction with our proprietary drug delivery method. Once formulated, we file for new patent applications on these formulated compounds that comprise our product candidates. Our patent portfolio includes patents and patent applications with claims directed to the pharmaceutical formulations, methods of use and methods of manufacturing for our product candidates.

Our goal is to become a leading specialty pharmaceutical company that develops and commercializes improved formulations of existing drugs using our patented oral spray technology. We believe that our technology has application to a broad number of therapeutic areas and product categories. Our strategy is to concentrate our product development activities primarily on pharmaceutical products which meet the following characteristics:

- Significant prescription sales already exist;
- Our proprietary novel drug delivery technology enhances the performance of the active ingredient of the target compound, potentially addressing unmet patient needs; and
- Applicability of an efficient regulatory pathway to approval using the 505(b)(2) pathway.

In today's environment of escalating drug development costs and time to market, we believe that the ability to bring products with some degree of differentiation and competitive advantage to the marketplace in a timely and cost-effective manner is a viable strategy.

Since inception, substantially all of our revenues have been derived from consulting activities, primarily in connection with product development for various pharmaceutical companies. More recently, we have begun to derive revenues from license fees and milestone payments stemming from our partnership agreements. Our future growth and profitability will be principally dependent upon our ability to successfully develop our product candidates and to market and distribute the final products either internally or with the assistance of strategic partners.

We have had a history of recurring losses, giving rise to an accumulated deficit as of March 31, 2010 of $84.1 million, as compared to $82.8 million as of December 31, 2009. We have had cash flow from operating activities of $102,000

and $(1,575,000) for the three months ended March 31, 2010 and 2009, respectively. As of March 31, 2010, we had negative working capital of $978,000 which includes a derivative liability of $913,000 as compared to $495,000 as of December 31, 2009, the net decrease in working capital of approximately $483,000 is primarily related to the derivative liability recorded as of March 31, 2010 offset by the December 31, 2009 conversion of the outstanding convertible debt, liquidated damages notes and associated accrued interest and proceeds from the sale of common stock.

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Throughout 2009, our reduced clinical development activities were limited to expenditures required to support our two approved products NitroMist™ and Zolpimist™ and minor expenditures to support formulation development activities for certain other products. We will seek to raise additional capital in 2010 to fund our operations and future development activities through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or, if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us. If we are unable to raise additional capital, and we do not use our existing working capital to fund our development plans, we will have sufficient cash on hand to fund operating costs through the fourth quarter 2010. We will need additional financing thereafter until we achieve profitability.

Our audited financial statements for the year ended December 31, 2009 were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. We believe that the cash inflows that have been generated from our financing transactions and our licensing transactions and any additional potential cash inflows that may be received during 2010 and 2011 will improve our ability to continue our operations as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

As previously disclosed on May 14, 2008, we received notice from the NYSE Amex LLC (formally known as the American Stock Exchange) indicating that we are not in compliance with certain of the NYSE Amex LLC continued listing standards. We submitted a plan of compliance with NYSE Amex LLC, which was accepted, and attempted to regain compliance with such plan during fiscal year 2009. On December 2, 2009, we formally notified NYSE Amex LLC of our intent to voluntarily withdraw our listing and registration due to our failure to regain compliance with the continued listing standards and our plan. On December 14, 2009, we filed a Form 25 voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009. On December 24, 2009, our common stock began trading on the Over-the-Counter Bulletin Board, or OTCBB, under its new ticker symbol on OTCBB as NVDL.OB.

Highlights for the three months ended March 31, 2010, and additionally through the date of filing of this Quarterly Report on Form 10-Q, include the following:

- Announced that on March 31, 2010, we would receive approximately $1.5 million in gross proceeds from our registered direct offering (the “Offering”) of 9,100,001 shares of common stock, par value $0.001 per share (the “Common Shares”), at a price of $0.165 per share. The investors received five-year warrants (the “Series A Warrants”) to purchase 4,550,001 shares of common stock with an exercise price of $0.25 per share and six-month warrants (the “Series B Warrants,” together with the Common Shares and the Series A Warrants, the “Securities”) to purchase 3,033,334 shares of common stock at an exercise price of $0.25 per share. As of March 31, 2010, we recorded net proceeds of $551,000 and a note receivable of $800,000 which cash proceeds were subsequently recorded on April 15, 2010, relating to the Offering. The exercise price of the Series A and Series B Warrants are subject to adjustment as provided by such warrants. The Offering closed on March 31, 2010 and we sold the Securities pursuant to an effective registration statement.
- During the three months ended March 31, 2010 we received net proceeds of $191,000 from Seaside 88, LP for the sale of our common stock. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP.
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On March 5, 2010 we received a milestone payment of $62,500 from Velcera. This milestone payment resulted from Velcera's global licensing agreement for the first canine pain management product delivered in a transmucosal mist form.

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Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the U.S. Food and Drug Administration, or FDA, or comparable regulatory authorities in foreign countries. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a New Drug Application, or NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2) NDA. We estimate that the development of new formulations of our pharmaceutical product candidates, including formulation, testing and submission of an NDA, will require significantly less time and lower investments in direct research and development expenditures than is the case for the discovery and development of new chemical entities. However, our estimates may prove to be inaccurate; or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all, and research and development expenditures may significantly exceed management's expectations.

It is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables, if at all. The failure or the delay of any one or more of our proposed products to achieve commercial viability would have a material adverse effect on us.

The successful development of our product candidates is highly uncertain. Estimates of the nature, timing and estimated expenses of the efforts necessary to complete the development of, and the period in which material net cash inflows are expected to commence from any of our product candidates are subject to numerous risks and uncertainties, including:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- results of future clinical trials;
- the expense of clinical trials for additional indications;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the expense and timing of regulatory approvals or changes in the regulatory approval process;
- the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technologies and market developments; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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We expect to spend significant amounts on the development of our product candidates and we expect our costs to increase if we restart programs to develop and ultimately commercialize our product candidates. The following table summarizes our product candidates:

	Active Ingredient or Class of Molecule	Indications	Stage of Development	Partner
Approved Products				
NitroMist™	nitroglycerin	Angina Pectoris	FDA Approved	Mist Acquisition, LLC
Zolpimist™	zolpidem	Insomnia	FDA Approved	ECR Pharmaceuticals Co., Inc.
Product Candidates				
Duromist™	sildenafil	Erectile Dysfunction	Preclinical development	-
Zensana™	ondansetron	Nausea/Vomiting	Clinical development	Hana Biosciences/Par Pharmaceutical, Inc./BioAlliance Pharma S.A.
NVD-201	sumatriptan	Migraines	Pilot efficacy study complete	-
NVD-301	Midazolam	Pre-Procedure Anxiety	Preclinical development	-

NitroMist™ (nitroglycerin lingual aerosol). This product is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease, and was approved by the FDA in November 2006. Previously, this product was partnered with Par Pharmaceutical, Inc., or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. Our former contract manufacturer for NitroMist™, INyX Pharma, filed for protection under the Chapter 11 bankruptcy laws in 2007, and ceased operations at its facility in Puerto Rico where our product was to be manufactured during 2008. As a result, we selected an alternative contract manufacturer, DPT Laboratories, and are in the process of transferring manufacturing operations to DPT. On October 27, 2009, the Company entered into a licensing and distribution agreement with privately-held Mist Acquisition, LLC (“Mist”) to manufacture and commercialize the NitroMist™ lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris. Under the terms of the agreement, Mist paid a $1,000,000 licensing fee upon execution of the agreement, milestone payments totaling an additional $1,000,000 over the next twelve months and ongoing performance payments of up to seventeen percent (17%) of net sales. In addition, Mist will assume the activities and costs necessary for the completion of the product transfer to DPT Laboratories.

Zolpimist™ (zolpidem oral spray). Zolpidem is the active ingredient in Ambien®, the leading hypnotic for insomnia marketed by Sanofi-Aventis. Our oral spray formulation of zolpidem was approved for the short-term treatment of insomnia by the FDA in December 2008. In October 2009, we received a Notice of Allowance from the United States

Patent and Trademark Office, or USPTO for claims which cover a method of treating insomnia by administering zolpidem to humans utilizing NovaMist™ Oral Spray technology. On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ in the United States and Canada. Under the terms of the agreement, we received a $3,000,000 licensing fee and will receive ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products.

Duromist™ (Sildenafil oral spray). Duromist contains sildenafil, the leading PDE-5 inhibitor for the treatment of erectile dysfunction marketed under the brand name Viagra®. We believe that an oral spray of sildenafil has the potential of a faster onset of action and a lower dose compared to tablets.

Erectile dysfunction occurs in approximately 18% of the male population with prevalence of over 50% in men over 65 years of age. PDE-5 inhibitors are effective in approximately 75% of the erectile dysfunction population. Sildenafil is the most popular molecule with over 50% market share in a erectile dysfunction market of over $3 billion.

Development is in progress for a formulation to be used in future clinical trials to begin in the second quarter 2010, with a development plan that would deliver a FDA approved product available for launch in the second quarter of 2012.

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Zensana™ (ondansetron oral spray). Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GlaxoSmithKline, or GSK. Through July 31, 2007, this product candidate was licensed to Hana Biosciences, who was overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, including the development and re-filing of the NDA in the United States. In addition, we entered into an Amended and Restated License Agreement with Hana Biosciences, pursuant to which Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock we acquired in connection with execution of the original license agreement with Hana Biosciences. Par had previously announced that it expected to complete clinical development on the revised formulation of Zensana™ during 2008, and expected to submit a new NDA for Zensana™ by the end of 2008. However, in November 2008, Par announced that it had completed bioequivalency studies on Zensana™ with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We have notified Hana and Par that under the terms of our agreement, they are required to return the product to us.

On May 19, 2008, we entered into an agreement with BioAlliance Pharma S.A., whereby BioAlliance acquired the European rights for our ondansetron oral spray. Under the terms of the agreement, BioAlliance paid us a license fee of $3,000,000 upon closing. We are eligible for additional milestone payments totaling approximately $24 million (an approval milestone of $5,000,000 and sales-related milestone payments of approximately $19 million) as well as a royalty on net sales. We anticipate that their development activities will not be initiated until development is completed in the United States.

Sumatriptan oral spray (NVD-201). Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GSK. A pilot PK study of NVD-201 with 9 healthy subjects, completed in the second half of calendar 2004, suggested that the formulation achieved plasma concentrations of sumatriptan in the therapeutic range. In September 2006 we announced positive results from an additional pilot pharmacokinetic study, with NVD-201 which demonstrated that NVD-201 achieves a statistically significant increase in absorption rate as compared with Imitrex® tablets. The rate of drug absorption is believed to be the most important predictor of the degree and speed of migraine relief. NVD-201 was evaluated in a four-arm, crossover pharmacokinetic study comparing 50mg Imitrex® tablets to 20mg and 30mg of the NVD-201 in 10 healthy male volunteers under fasting conditions. At least 90% of subjects receiving NVD-201 had detectable drug levels at three minutes post-dosing, while at the same timepoint, only 10% of subjects receiving 50mg Imitrex® tablets had detectable drug levels. These differences are statistically significant. At 3 to 6 minutes post dosing, all NVD-201 groups had statistically significantly higher mean concentration levels compared to 50mg Imitrex® tablets. Using published data for the currently marketed Imitrex® nasal spray as a proxy for therapeutic blood levels, we observed that by 6 minutes post-dosing, 100% of the 20mg NVD-201 users achieved these critical plasma concentration levels while none of the subjects from the Imitrex® tablet group did so by this timepoint. This result was also statistically significant. Furthermore, the study indicates up to a 50% increase in relative bioavailability of NVD-201 in comparison to the Imitrex® tablet. Additionally, the pharmacokinetics of 20mg NVD-201 after a meal were evaluated. NVD-201 was well tolerated.

While Imitrex® nasal spray was not included in this clinical study, the following represents a discussion of the results of our clinical study as compared to published data for Imitrex® nasal spray. Time to the first peak plasma concentration of sumatriptan -- which represents drug absorbed directly across the oral mucosa -- was approximately 70% faster with the 20mg NVD-201 than what has been reported in the literature for the same dose of the Imitrex® nasal spray (6 min. vs. 20 min.). The mean concentration level achieved during this critical first phase of absorption is

approximately 30% greater for the NVD-201 than what was observed in published studies of the nasal spray (10.9 ng/mL vs. 8.5 ng/mL). Relative bioavailability after administration of 20mg NVD-201 appears to be greater than published estimates for the same dose of the Imitrex® nasal spray.

In September 2008, we announced the results from a pilot efficacy study for NVD-201. This was a multi-center, active control, open-label, dose-ranging, efficacy and safety study. Subjects received up to 5 treatments, comprising single doses of the following: Imigran® 50-mg tablets, Imigran® 100-mg tablets, NVD-201 20-mg, NVD-201 30-mg, and NVD-201 40-mg. Their response to Imigran® 50-mg tablets determined whether they were eligible to receive the other four treatments. Patients recorded the severity of each migraine attack on the same 4-point scale immediately before dosing and at 15, 30, 60, 90, 120, and 240 minutes, and at 24 hours post-dosing. Associated symptoms (nausea, vomiting, photophobia, and phonophobia) were also recorded immediately before dosing and at 30, 60, 90 and 120 minutes post-dosing. All dosing was done on an outpatient basis and patients returned to the clinic between migraine attacks.

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In the primary analysis of efficacy, the percentage of patients responding to treatment at or before 60 minutes post-dosing, there was a statistically significant greater percentage of subjects receiving the 30- and 40-mg doses of NVD-201 with a reduction in headache pain compared to those receiving the 50-mg s Imigran® tablet (42% and 46%, respectively, vs 12%; P<0.011), and was comparable to the percentage who responded to the higher (100 mg) dose of the tablet formulation (42%). Significantly more patients had responded to all three doses of NVD-201 than to 50-mg Imigran® tablet by 90 minutes post-dosing (57% to 70.0% vs 32%; P<0.028) and all three oral spray doses were comparable to the 100-mg tablet. There were no treatment differences by 2 hours after dosing, when 68% to 77% of patients had responded irrespective of treatment.

Compared to 50-mg Imigran® tablet, at least one dose of NVD-201 also significantly increased percentage of patients who were pain free by 1 to 2 hours post-dosing, with the response ratio indicating significantly faster complete pain relief for the 40-mg dose, and significantly more patients had complete pain relief without use of rescue medication after receiving any dose of NVD-201. In addition, after one or more doses of NVD-201, the percentage of patients who were asymptomatic was significantly increased, and the percentages who experienced nausea, photophobia, or phonophobia were significantly decreased. NVD-201 was comparable to the 100-mg tablet on all the above measures.

We believe NVD-201 may provide clinical benefits to migraine sufferers including, possibly, faster relief than Imitrex® tablets as well as greater tolerability than triptan nasal sprays. Further, if proven to be safe and effective, we believe NVD-201 may be attractive to patients who have trouble taking oral medications due to nausea and vomiting caused by the migraine attack. Previously, we were targeting an NDA submission for our sumatriptan product candidate in the first half of calendar 2008; however, due to funding constraints and other higher priorities associated with our current product pipeline, we have not progressed our development efforts.

We will continue to evaluate this program when sufficient additional funding becomes available.

Midazolam oral spray (NVD-301). NVD-301 contains midazolam which is the leading benzodiazepine used for sedation during diagnostic, therapeutic and endoscopic procedures. We believe that NVD-301 has the potential to be an easy-to use, rapid onset product useful to relieve the pre-procedure anxiety suffered by many patients prior to undergoing a wide variety of procedures performed in hospitals, imaging centers, ambulatory surgery centers and dental offices.

Annually, there are approximately 40 million invasive procedures performed in the ambulatory surgical setting, > 25 million MRI/CT scans and over 90 million pediatric dental procedures performed. Pre- procedure anxiety occurs in approximately 60% of children undergoing surgery and is associated with an increase in post-surgical complications including delirium, pain and sleep disorders, as well as higher levels of use of post-surgical medications. Anxiety interferes with approximately 30% of MRI scans with 5-10% of scans not completed due to anxiety. Pre-procedure anxiety is the number one reason for the use of sedation in dental procedures.

As of the current date, we have not yet secured sufficient financing to resume our clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

Propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. On July 10, 2007, Manhattan Pharmaceuticals, our licensee, announced its intention to pursue appropriate sub-licensing opportunities for this product candidate.

Veterinary. Our veterinary initiatives are being carried out largely by our partner, Velcera, Inc., or Velcera. In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health. The agreement calls for Novartis Animal Health to develop, register and commercialize a novel canine

product utilizing Velcera's Promist™ platform, which is based on our patented oral spray technology. On March 5, 2008, Velcera announced that it had received notice from Novartis that it was terminating the agreement without cause. On August 24, 2009, we issued a press release to announce that we received a milestone payment of approximately $150,000 from Velcera, Inc. relating to our License and Development agreement dated June 22, 2004. This milestone payment resulted from Velcera's announced global licensing agreement for the first canine pain management product delivered in a transmucosal mist form. On March 5, 2010 the Company received another milestone payment of $62,500. These milestone payments resulted from Velcera's global licensing agreement for the first canine pain management product delivered in a transmucosal mist form.

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As discussed above, certain of our product candidates are in early stages of clinical development and some are in preclinical testing. These product candidates are continuously evaluated and assessed and are often subject to changes in formulation and technology. As a result, these product candidates are subject to a more difficult, time-consuming and expensive regulatory path in order to commence and complete the preclinical and clinical testing of these product candidates as compared to other product candidates in later stages of development.

CRITICAL ACCOUNTING POLICIES

USE OF ESTIMATES - The accompanying condensed financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. This requires our management to make estimates about the future resolution of existing uncertainties that affect the reported amounts of assets, liabilities, revenues and expenses which in the normal course of business are subsequently adjusted to actual results. Actual results could differ from such estimates. In preparing these condensed financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the condensed financial statements giving due regard to materiality.

CASH AND CASH EQUIVALENTS – Cash equivalents consist of money market instruments with original maturities of three months or less when purchased. We maintain our cash and cash equivalents with several financial institutions. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed on demand and are maintained with high quality financial institutions, therefore reducing credit risk.

REVENUE RECOGNITION – We receive revenue from consulting services and license agreements. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured. Upfront license agreement payments are initially deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned.

DEFERRED FINANCING COSTS – We capitalize the costs related to the issuance of our convertible notes, and amortize such deferred costs to interest expense on a straight-line basis over the life of the related notes. We capitalized approximately $238,000 of deferred financing costs associated with the issuance of our convertible notes during 2008. We amortized approximately $22,000 to expense during the three months ended March 31, 2009.

WARRANTS ISSUED WITH FINANCING – The value of warrants and the intrinsic value of beneficial conversion rights arising from the issuance of convertible notes are determined by allocating an appropriate portion of the proceeds received from the debt instruments to the debt and warrants based on their relative fair value, which was determined using the Black-Scholes model. The Company adopted Accounting Standards Codification (“ASC”) 815-40-15 on January 1, 2009. ASC 815-40-15 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity’s own stock. The adoption of ASC 815-40-15 resulted in an adjustment to opening accumulated deficit in the amount of $360,000 to reclassify the fair value of certain outstanding warrants from stockholders’ deficiency to liability. The warrants affected expired during the first quarter of 2009 and, as a result, the fair value of the warrant liability was reduced to zero and recognition of Other Income of $360,000 at the end of the reporting period. Relating to the March 31, 2010 equity financing, the Company also issued Series A and B warrants that provide for a possible adjustment in exercise price for subsequent stock issuances. The Company estimated the fair value of the Warrants as of March 31, 2010 to be $913,000 and recorded a liability and corresponding reduction in additional paid in capital. Two classes of warrants were issued; Series A warrants totaling 4,550,001 with a term of 5 years and Series B warrants totaling 3,033,334 with a term of 0.5 years. The exercise price for both the Series A and B warrants are $0.25, subject to adjustment. In accordance with this pronouncement the Company estimated the fair value of the related warrants to purchase shares of the Company’s common stock at $755,992 and $156,719, respectively. As of March 31, 2010 the fair values of these derivatives totaled $913,000 and

are recorded in the accompanying condensed balance sheet as of March 31, 2010 as derivative liability.

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VALUATION OF LONG-LIVED ASSETS – We assess the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Our long-lived assets as of March 31, 2010 were represented by property and equipment, as we have no intangible assets on our balance sheet. Factors we consider important which could trigger an impairment review include the following:

- significant underperformance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends; and
- significant decrease in the market value of the assets.

The impairment test is based upon a comparison of the estimated undiscounted cash flows to the carrying value of the long-lived assets. If we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment based on projected discounted cash flows. The cash flow estimates used to determine the impairment, if any, contain management's best estimate using appropriate assumptions and projections at that time. Net long-lived property and equipment as of March 31, 2010 was $298,000. We reviewed our long-lived property and equipment as of March 31, 2010 and have determined that their estimated fair value exceeds the carrying amount of such assets; therefore, we have not recognized an impairment loss for our long-lived property and equipment.

STOCK-BASED COMPENSATION –The Company calculates the fair value of stock based compensation using the Black-Scholes method. Stock based compensation costs are recorded as earned for all unvested stock options outstanding. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date. We recorded share-based compensation expense of $205,000 for the three months ended March 31, 2010 and $149,000 for the three months ended March 31, 2009. We will continue to incur share-based compensation charges in future periods. As of March 31, 2010, unamortized share-based compensation expense of $664,700 remains to be recognized, which is comprised of $394,600 related to non-performance based stock options to be recognized over a weighted average period of 1.5 years, $104,500 related to restricted stock to be recognized over a weighted average period of 1.1 years, and $165,600 related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

We used the following weighted average assumptions in determining fair value under the Black-Scholes model for grants of all stock options in the respective periods:

	Three Months Ended	
	March 31, 2010	March 31, 2009
Expected volatility	—	83%
Dividend yield	—	0%

Expected term (years)	—	3.06
Risk-free interest rate	—	1.7%

The above table represents the weighted-average assumptions for all stock options granted during the three months ended March 31, 2009. The Company did not grant any stock options during the three months ended March 31, 2010.

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Expected volatility is based on historical volatility of our common stock. The expected term of options is estimated based on the average of the vesting period and contractual term of the option. The risk-free rate is based on U.S. Treasury yields for securities in effect at the time of grant with terms approximating the expected term until exercise of the option. In addition, the fair value of stock options granted is recognized as expense over the service period, net of estimated forfeitures. We are utilizing a 5% forfeiture rate, which we believe is a reasonable assumption to estimate forfeitures. However, the estimation of forfeitures requires significant judgment, and to the extent actual results or updated estimates differ from our current estimates, the effects of such resulting adjustment will be recorded in the period estimates are revised. No options were exercised during the three months ended March 31, 2010 or March 31, 2009.

RESEARCH AND DEVELOPMENT EXPENSES - Research and development costs are expensed as incurred.

NEW ACCOUNTING PRONOUNCEMENTS – In April 2010, an accounting standard update was issued to provide guidance on defining a milestone and determining when it is appropriate to apply the milestone method of revenue recognition for research and development transactions. Vendors can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period the milestone is achieved if the milestone meets all the criteria stated in the guidance to be considered substantive and must be considered substantive in its entirety. The amendments in this update will be effective prospectively for milestones achieved in fiscal years and interim periods beginning on or after June 15, 2010, with early adoption permitted.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2010 AND MARCH 31, 2009

License fees and milestone fees earned for the three months ended March 31, 2010 were $129,000 as compared to $66,000 for the three months ended March 31, 2009. Increase was due to a milestone payment received from Velcera.

Research and development expenses for the three months ended March 31, 2010 were $447,000 as compared to $826,000 for the three months ended March 31, 2009. Research and development costs consist primarily of salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses for the three months ended March 31, 2010 and March 31, 2009.

	Three Months Ended	
	March 31, 2010	March 31, 2009
NitroMist™	$ —	$ 85,000
Zolpimist™	64,000	69,000
Sumatriptan	—	170,000
Zensana™	—	5,000
Duromist™	96,000	—
Other research and development costs	134,000	78,000
Internal costs	153,000	419,000
Total research and development	$ 447,000	$ 826,000

expenses

In the preceding table, research and development expenses are set forth in the following categories:

- NitroMist™, Zolpimist™, Sumatriptan and Duromist™ - third-party direct project expenses relating to the development of the respective product candidates. The majority of our research and development resources were devoted to Zolpimist™ and Duromist™. We have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007 and continuing into 2010. We have initiated clinical activity on Duromist™ and plan to expand project activity however we believe that we will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities;

- Zensana™ - third-party direct project expenses relating to the development of Zensana™. As our partner for the Zensana™, Par, is overseeing all clinical development and regulatory approval activities, we do not expect to devote a significant amount of resources to this product candidate;

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- Other research and development costs – direct expenses not attributable to a specific product candidate; and

- Internal costs – costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

Research and development expenses in the three months ended March 31, 2010 decreased primarily as a result of the following items:

- $85,000 decrease in costs associated with our NitroMist™ product as in the three months ended March 31, 2010 due to the product licensed in Q4 2009;

- $5,000 decrease in product development costs for our Zolpimist™ product in the three months ended March 31, 2010 due to the product licensed in Q4 2009;

- $170,000 decrease in product development costs for our Sumatriptan product candidate, due to delayed activity on this project;

- $96,000 increase in product development costs for our Duromist™ product candidate as development activities were initiated during Q1 2010;

- $266,000 decrease in internal costs is due to restructuring activities, new office facility and reduced headcount.

Consulting, selling, general and administrative expenses for the three months ended March 31, 2010 were $974,000 as compared to $1,258,000 for the three months ended March 31, 2009. General and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The decrease in general and administrative expenses is primarily attributable to the Company's employee-related costs due to decrease in headcount and relocation of facilities.

Primarily as a result of the factors described above, total expenses for the three months ended March 31, 2010 were $1,421,000, as compared to $2,084,000 for the three months ended March 31, 2010.

The resulting net loss for the three months ended March 31, 2010 was $1,292,000 as compared to $2,139,000 for the three months ended March 31, 2009.

LIQUIDITY AND CAPITAL RESOURCES

From our inception, our principal sources of capital have been consulting revenues, private placements and public offerings of our securities, as well as loans and capital contributions from our principal stockholders. We have had a history of recurring losses, giving rise to an accumulated deficit as of March 31, 2010 of $84,058,000, as compared to $82,766,000 as of December 31, 2009. We have had cash flow provided by (used in) operating activities of $102,000 and $(1,575,000) for the three months ended March 31, 2010 and 2009, respectively. As of March 31, 2010, we had working capital deficiency of $978,000 which includes a derivative liability of $913,000, as compared to working capital deficiency of $495,000 as of December 31, 2009, representing a net decrease in working capital of approximately $483,000.

Net cash provided by (used in) operating activities was $102,000 for the three months ended March 31, 2010, as compared to $(1,575,000) for the three months ended March 31, 2009. The increase was primarily due to the $1,057,000 received in first quarter 2010 from the sale of net operating losses in the prior quarter and overall

reduction in expenses. Net cash flows provided by financing and investing activities were $882,000 for the three months ended March 31, 2010, primarily due to net proceeds received relating to issuance of common stock during the first quarter 2010.

Until and unless our operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved drugs by partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs.

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We received $1,475,000 in gross proceeds on May 30, 2008 from the Initial Closing of a convertible note financing with certain funds affiliated with ProQuest, and received $2,525,000 in gross proceeds on October 17, 2008 from the Subsequent Closing of such convertible note financing. The convertible notes issued in the Initial Closing matured on November 30, 2008 and, in the Subsequent Closing, on April 17, 2009. On April 29, 2009, we remitted $1,000,000 to ProQuest against the $4,000,000 of convertible notes issued during 2008. On December 31, 2009, we entered into an amendment agreement with ProQuest to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damages notes, in each case, plus all accrued interest, in an aggregate amount equal to $3,657,000 to 23,237,083 shares of our common stock.

We entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP will purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than or equal to the stated floor price of $0.25 per share. We have received $1,255,000 in gross proceeds for the closings that have occurred through March 31, 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP.

On March 5, 2010, we received a milestone payment of $62,500 and on August 24, 2009, we received a milestone payment of approximately $150,000 from Velcera, Inc. relating to our License and Development agreement dated June 22, 2004. These milestone payments resulted from Velcera's recently announced global licensing agreement for the first canine pain management product delivered in a transmucosal mist form.

On October 27, 2009, we entered into a licensing and distribution agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize the NitroMist™ lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris. Under the terms of the agreement, we received a $1,000,000 licensing fee upon execution of the agreement, and will receive milestone payments totaling an additional $1,000,000 over the next twelve months and ongoing performance payments of up to seventeen percent (17%) of net sales subject to potential reduction based upon the terms of the Agreement. The Agreement contains customary termination provisions. In addition, the Agreement may be terminated by Mist for any reason upon written notice to us, which will be effective 180 days from the date of receipt of such notice, provided that Mist may not terminate until the second anniversary after the first commercial sale of NitroMist™ by Mist or its affiliates.

Through a separate license agreement with Mist, Akrimax Pharmaceuticals, LLC will receive the exclusive right to manufacture, distribute, market and sell NitroMist™ in the United States, Canada and Mexico. Under the terms of the Agreement, we will receive a percentage of any income received by Mist under any sublicense agreement relating to NitroMist™.

On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ in the United States and Canada. ZolpiMist™ is our oral spray formulation of zolpidem tartrate, which was approved by the FDA in December of 2008. Under the terms of the agreement, ECR paid us $3,000,000 upon the execution of the agreement and ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products, subject to the terms of the agreement. A performance milestone will be due us if net sales reach a certain level. We have an opportunity to co-promote zolpidem tartrate oral spray in the United States and Canada with ECR's consent, and retain commercialization rights for all other territories. ECR will assume responsibility for manufacturing the product for commercialization in the United States and Canada, including any activities required from the date of the agreement. The agreement contains customary termination provisions. In addition, the agreement may be terminated by ECR for any reason upon written notice to us, which will be effective 180 days from the date of receipt of such notice, provided that ECR may not terminate until the second anniversary after the first commercial sale of ZolpiMist™ by ECR or its affiliates.

On March 31, 2010, we announced that we would receive approximately $1.5 million in gross proceeds in a registered direct offering (the “Offering”) of 9,100,001 shares of common stock, par value $0.001 per share (the “Common Shares”), at a price of $0.165 per share. The investors also received five-year warrants (the “Series A Warrants”) to purchase 4,550,001 shares of common stock with an exercise price of $0.25 per share and six-month warrants (the “Series B Warrants,” together with the Common Shares and the Series A Warrants, the “Securities”) to purchase 3,033,334 shares of common stock at an exercise price of $0.25 per share. As of March 31, 2010, we recorded net proceeds of $551,000 and a note receivable of $800,000 which cash proceeds were subsequently received on April 15, 2010, relating to the Offering. The exercise price of the Series A and Series B Warrants are subject to adjustment as provided by such warrants. The Offering closed on March 31, 2010 and we sold the Securities pursuant to an effective registration statement.

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We will seek to raise additional capital in 2010 to fund our operations and future development activities through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or, if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us. If we are unable to raise additional capital, and we do not use our existing working capital to fund our development plans, we will have sufficient cash on hand to fund operating costs through the fourth quarter 2010.

Our audited financial statements for the fiscal year ended December 31, 2009 were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. We believe that the cash inflows that have been generated from our financing transactions and our licensing transactions and any additional potential cash inflows that may be received during 2010 will improve our ability to continue our operations as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

As previously disclosed on May 14, 2008, we received notice from the NYSE Amex LLC (formally known as the American Stock Exchange) indicating that we are not in compliance with certain of the NYSE Amex LLC continued listing standards. We submitted a plan of compliance with NYSE Amex LLC, which was accepted, and attempted to regain compliance with such plan during fiscal year 2009. On December 2, 2009, we formally notified NYSE Amex LLC of our intent to voluntarily withdraw our listing and registration due to our failure to regain compliance with the continued listing standards and our plan. On December 14, 2009, we filed a Form 25 voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009. On December 24, 2009, our common stock began trading on the Over-the-Counter Bulletin Board, or OTCBB, under its new ticker symbol on OTCBB as NVDL.OB.

OFF-BALANCE SHEET ARRANGEMENTS

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, results of operations, liquidity or capital resources.

CONTRACTUAL OBLIGATIONS

Our major outstanding contractual obligations relate to our operating leases, employment agreements, consulting agreements, and license agreements with our strategic partners. As previously disclosed, our Board of Directors appointed Steven B. Ratoff as President and Chief Executive Officer effective January 1, 2010 and Mr. Ratoff will continue to serve as Interim Chief Financial Officer. Additionally, beginning February 1, 2010, we entered into a one (1) year lease agreement with Regus Management Group LLC for approximately 5,000 square feet of office space in Bridgewater, New Jersey.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest primarily in short-term, highly-rated investments, including U.S. government securities and certificates of deposit guaranteed by banks. Our market risk exposure consists principally of exposure to changes in interest rates. Because of the short-term maturities of our investments, however, we do not believe that a decrease in interest rates would have a significant negative impact on the value of our investment portfolio.

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ITEM 4T. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures or controls and other procedures that are designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, or Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission, or SEC, rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that a company files or submits under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and interim chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of March 31, 2010. Based on this evaluation, our chief executive officer and interim chief financial officer concluded that as of March 31, 2010, our disclosure controls and procedures were effective at providing reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and (ii) accumulated and communicated to our management, including our chief executive officer and interim chief financial officer, as appropriate, to allow timely decisions regarding disclosure.

Changes in Internal Controls

During the three months ended March 31, 2010, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 1A. RISK FACTORS

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below, elsewhere in this report, and in any documents incorporated in this report by reference.

RISKS RELATED TO OUR BUSINESS

OUR AUDITORS HAVE EXPRESSED SUBSTANTIAL DOUBT ABOUT OUR ABILITY TO CONTINUE AS A GOING CONCERN.

Our audited financial statements for the year ended December 31, 2009, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report on our 2009 Financial Statements has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Given the recent downturn in the economy, such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

WE WILL REQUIRE SIGNIFICANT ADDITIONAL CAPITAL TO FUND OUR OPERATIONS.

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, and preclinical studies.

We have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007 and continuing through the first quarter of 2010, limiting our expenditures primarily to Nitromist™, Zolpimist™ and recently on Duromist™. During the first quarter 2010, we have initiated product development of Duromist™, an oral spray of sildenafil citrate, for the treatment of erectile dysfunction. We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing, to complete the development of this product and other products in our product development pipeline.

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On October 27, 2009, we entered into a licensing agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize the NitroMist™ lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris. Under the terms of the agreement, we received a $1,000,000 licensing fee upon execution of the agreement, and we will receive milestone payments totaling an additional $1,000,000 over the next twelve months and ongoing performance payments of up to seventeen percent (17%) of net sales.

On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ in the United States and Canada. Under the terms of the agreement, we received a $3,000,000 licensing fee and will receive ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products.

In addition, on December 31, 2009, we entered into an amendment agreement with ProQuest Investments L.P. and its affiliates, referred to herein as ProQuest, to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damages notes, in each case, plus all accrued but unpaid interest, in an aggregate amount equal to $3,657,000 to 23,237,083 shares of our common stock as of December 31, 2009.

We have entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP will purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than or equal to the stated floor price of $0.25 per share. We have received $1,055,000 in gross proceeds for the closings that have occurred through December 31, 2009. As of March 24, 2010, we have received $200,140 in gross proceeds for 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP as of such date.

On March 31, 2010, we announced we would receive approximately $1.5 million in gross proceeds from our registered direct offering (the “Offering”) of 9,100,001 shares of common stock, par value $0.001 per share (the “Common Shares”), at a price of $0.165 per share. The investors received five-year warrants (the “Series A Warrants”) to purchase 4,550,001 shares of common stock with an exercise price of $0.25 per share and six-month warrants (the “Series B Warrants,” together with the Common Shares and the Series A Warrants, the “Securities”) to purchase 3,033,334 shares of common stock at an exercise price of $0.25 per share. As of March 31, 2010, we recorded net proceeds of $551,000 and a note receivable of $800,000 which was subsequently received on April 15, 2010, relating to the Offering. The exercise price of the Series A and Series B Warrants are subject to adjustment as provided by such warrants. The Offering closed on March 31, 2010 and we sold the Securities pursuant to an effective registration statement.

We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

If we are unable to raise additional funds, we will need to do one or more of the following:

- further delay, scale-back or eliminate some or all of our research and product development programs;
- license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;

- attempt to sell our company;
- cease operations; or
- declare bankruptcy.

We are seeking to raise additional capital in 2010 to fund our operations and future development. A capital raise could include the securing of funds through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us.

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If we are unable to raise additional capital, and we do not use our existing working capital to fund our development plans, we will have sufficient cash on hand to fund operating costs through the fourth quarter 2010.

WE WILL REQUIRE SIGNIFICANT CAPITAL FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION IN THE NEAR TERM.

The research, development, testing and approval of our product candidates involve significant expenditures, and, accordingly, we require significant capital to fund such expenditures. Due to our small revenue base, negative working capital and, until recently, our relative inability to increase the number of development agreements with pharmaceutical companies, we have been unable to pursue aggressively our product development strategy. Until and unless our operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand, license agreements and sale of equity securities. Our long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs, or on terms favorable to us.

Although we have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007 and continuing through the first quarter of 2010, we have limited our expenditures primarily to Nitromist™, Zolpimist™ and recently on Duromist™. During the first quarter 2010, we have initiated product development of Duromist™, an oral spray of sildenafil citrate, for the treatment of erectile dysfunction. We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing, to complete the development of this product and other products in our product development pipeline. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities;

WE ARE A PRE-COMMERCIALIZATION COMPANY, HAVE A LIMITED OPERATING HISTORY AND HAVE NOT GENERATED ANY REVENUES FROM THE SALE OF PRODUCTS TO DATE.

We are a pre-commercialization specialty pharmaceutical company developing oral spray formulations of a broad range of marketed treatments. There are many uncertainties and complexities with respect to such companies. We have not generated any revenue from the commercial sale of our proposed products, however our licensees for Nitromist and Zolpimist are expected to commercially launch these products in the second half of 2010. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain U.S. Food and Drug Administration, or FDA, approval and achieve market acceptance of our proposed products and respond to competition. The filing of a New Drug Application, or NDA, with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted. We cannot be certain as to when to anticipate commercializing and marketing any of our product candidates in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

We had an accumulated deficit as of March 31, 2010 of approximately $84,058,000. We incurred losses in each of our last ten fiscal years, including net losses of approximately $1,292,000 for the three months ended March 31, 2010, $7,577,000 for the year ended December 31, 2009, $9,586,000 for the year ended December 31, 2008, and $16,963,000 for the year ended December 31, 2007. Additionally, we have reported negative cash flows from operations of approximately $573,000 for the three months ended March 31, 2010, $1,578,000 for the year ended

December 31, 2009, $5,533,000 for the year ended December 31, 2008, and $15,240,000 for the year ended December 31, 2007. We anticipate that, even with our limited research and development activities, we could incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates, obtain the required regulatory approvals and manufacture, market and sell our product candidates.

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OUR ADDITIONAL FINANCING REQUIREMENTS COULD RESULT IN DILUTION TO EXISTING STOCKHOLDERS.

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our existing stockholders. Given the recent downturn in the economy, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of our common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

OUR TECHNOLOGY PLATFORM IS BASED SOLELY ON OUR PROPRIETARY DRUG DELIVERY TECHNOLOGY. OUR ONGOING CLINICAL TRIALS FOR CERTAIN OF OUR PRODUCT CANDIDATES MAY BE DELAYED, OR FAIL, WHICH WILL HARM OUR BUSINESS.

Our strategy is to concentrate our product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of our proprietary, novel drug delivery technology could potentially enhance speed of onset of therapeutic effect, could potentially reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect and improve patient convenience or compliance.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. In addition, companies may be unable to enroll patients quickly enough to meet expectations for completing clinical trials. The timing and completion of current and planned clinical trials of our product candidates depend on, among other factors, the rate at which patients are enrolled, which is a function of many factors, including:

- the number of clinical sites;
- the size of the patient population;
- the proximity of patients to the clinical sites;
- the eligibility criteria for the study;
- the existence of competing clinical trials; and
- the existence of alternative available products.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both.

THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.

As of May 1, 2010, ProQuest, a significant stockholder, directly and indirectly, of us, beneficially owns approximately 43.8% of our outstanding common stock (assuming full exercise of certain warrants held by ProQuest). As such, ProQuest may be deemed to be our affiliate. Mr. Steven B. Ratoff, our Chairman, President, Chief Executive Officer and Interim Chief Financial Officer, has served as a venture partner with ProQuest since December 2004, although he

has no authority for investment decisions by ProQuest.

OUR BUSINESS AND REVENUE IS DEPENDENT ON THE SUCCESSFUL DEVELOPMENT OF OUR PRODUCTS.

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability to successfully raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our product candidates. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our product candidates and expect these expenses to result in continuing and significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. We may not be able to raise additional financing, increase revenues significantly, or achieve profitable operations.

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SOME OF OUR PRODUCT CANDIDATES ARE IN EARLY STAGES OF CLINICAL DEVELOPMENT AND SOME ARE IN PRECLINICAL TESTING, WHICH MAY AFFECT OUR ABILITY OR THE TIME WE REQUIRE TO OBTAIN NECESSARY REGULATORY APPROVALS.

Some of our product candidates are in early stages of clinical development and some are in preclinical testing. These product candidates are continuously evaluated and assessed and are often subject to changes in formulation and technology. The regulatory requirements governing these types of products may be less well defined or more rigorous than for conventional products. As a result, we may experience delays with our preclinical and clinical testing, and a longer and more expensive regulatory process in connection with obtaining regulatory approvals of these types of product candidates as compared to others in our pipeline at later stages of development. These delays may negatively affect our business and operations.

WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS.

Our principal efforts are the development of obtaining regulatory approvals for and licensing our product candidates. We anticipate that marketing activities by our licensees for our two approved products will not begin until the second half of 2010.

There can be no assurances that our licensees will successfully market out two approved product candidates, or that such product candidates will become commercially available.

WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT.

We have not completed the development of our product candidates and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such product candidates must be obtained before the product candidates will become available for commercial sale. We have recently obtained strategic partners for both NitroMist™ and Zolpimist™. Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. We may not be able to successfully develop any one or more of our product candidates or develop such product candidates on a timely basis. Further, such product candidates may not be commercially accepted if developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any product candidates, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations.

WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE.

We have no experience in marketing or distribution at the consumer level of our product candidates. Moreover, we do not have the financial or other resources to undertake extensive marketing and advertising activities. Accordingly, we intend generally to rely on marketing arrangements, including possible joint ventures or license or distribution arrangements with third-parties. Except for our agreements with Mist, ECR, BioAlliance, Par, Manhattan Pharmaceuticals, Velcera and Hana Biosciences, we have not entered into any significant agreements or arrangements with respect to the marketing of our product candidates. We may not be able to enter into any such agreements or similar arrangements in the future and we may not be able to successfully market our products. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

We have stated our intention to possibly market our own products in the future, although we have no such experience to date. Substantial investment will be required in order to build infrastructure and provide resources in support of marketing our own products, particularly the establishment of a marketing force. If we do not develop a marketing force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products. The establishment of our own marketing force, or a strategy to rely on third party marketing arrangements, could adversely affect our profit margins.

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WE MUST COMPLY WITH GOOD MANUFACTURING PRACTICES.

The manufacture of our pharmaceutical products under development will be subject to current Good Manufacturing Practices, or cGMP, prescribed by the FDA, pre-approval inspections by the FDA or comparable foreign authorities, or both, before commercial manufacture of any such products and periodic cGMP compliance inspections thereafter by the FDA. We, or any of our third party manufacturers, may not be able to comply with cGMP or satisfy pre- or post-approval inspections by the FDA or comparable foreign authorities in connection with the manufacture of our product candidates. Failure or delay by us or any such manufacturer to comply with cGMP or satisfy pre- or post-approval inspections would have a material adverse effect on our business and operations.

WE ARE DEPENDENT ON OUR SUPPLIERS.

We believe that the active ingredients used in the manufacture of our product candidates are presently available from numerous suppliers located in the U.S., Europe, India and Japan. We believe that certain raw materials, including inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with our spray products currently are available only from sole source suppliers. Although we do not believe we will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our product candidates, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials.

In February 2008, we entered into a Master Services Agreement with Rechon Life Sciences (Malmo, Sweden), whereby Rechon will provide services related to the manufacturing development and the manufacture of clinical supplies for our products. Rechon provides these services on a fee-for-service basis.

On December 28, 2009, DPT Laboratories became our contract manufacturer for Duromist, sildenafil citrate oral spray.

With respect to other suppliers, we operate primarily on a purchase order basis beyond which there is no contract memorializing our purchasing arrangements. The inability to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies, or the failure of DPT Laboratories, or Rechon Life Sciences to comply with their supply obligations to us, could have a material adverse effect on our ability to arrange for the manufacture of formulated products. In addition, development and regulatory approval of our products are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the originally specified supplier, which may result in manufacturing delays. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

FAILURE TO ACHIEVE AND MAINTAIN EFFECTIVE INTERNAL CONTROLS IN ACCORDANCE WITH SECTION 404 OF THE SARBANES-OXLEY ACT OF 2002 COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS AND OPERATING RESULTS. IN ADDITION, CURRENT AND POTENTIAL STOCKHOLDERS COULD LOSE CONFIDENCE IN OUR FINANCIAL REPORTING, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR STOCK PRICE.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results and financial condition could be harmed.

We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which requires annual management assessments of the effectiveness of our internal controls over financial reporting. During the course of our testing we may identify deficiencies which we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002 for compliance with the requirements of Section 404. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Failure to achieve and maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock.

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COMPLIANCE WITH CHANGING REGULATION OF CORPORATE GOVERNANCE AND PUBLIC DISCLOSURE MAY RESULT IN ADDITIONAL EXPENSES.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new regulations promulgated by the Securities and Exchange Commission, or SEC, and NYSE Amex, or NYSE Amex rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In particular, our recent efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our independent registered public accounting firm's audit of that assessment requires the commitment of significant financial and managerial resources. In addition, it has become more difficult and more expensive for us to obtain director and officer liability insurance. We expect these efforts to require the continued commitment of significant resources. Further, our Board members, Chief Executive Officer and Interim Chief Financial Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could harm our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may be harmed.

WE FACE INTENSE COMPETITION.

The markets which we intend to enter are characterized by intense competition. We, or our licensees, may be competing against established, larger and/or better capitalized pharmaceutical companies with currently marketed products which are equivalent or functionally similar to those we intend to market. Prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with our product candidates. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced dosage from technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. Most of our prospective competitors possess substantially greater financial, technical and other resources than we do. Moreover, many of these companies possess greater marketing capabilities than we do, including the resources necessary to enable them to implement extensive advertising campaigns. We may not be able to compete successfully with such competitors.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. Our competitors may be more successful in receiving third party reimbursements from government agencies and others for their commercialized products which are similar to our products. If we cannot receive third party reimbursement for our products, we may not be able to commercialize our products. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

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LIMITED PRODUCT LIABILITY INSURANCE COVERAGE MAY AFFECT OUR BUSINESS.

We may be exposed to potential product liability claims by end-users of our products. Although we obtain product liability insurance per contractual obligations, before the commercialization of any of our product candidates, we cannot guarantee such insurance will be sufficient to cover all possible liabilities to which we may be exposed. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock. In addition, certain food and drug retailers require minimum product liability insurance coverage as a condition precedent to purchasing or accepting products for retail distribution. Product liability insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. Failure to satisfy such insurance requirements could impede the ability of us or our distributors to achieve broad retail distribution of our product candidates, which could have a material adverse effect on us.

EXTENSIVE GOVERNMENT REGULATION MAY AFFECT OUR BUSINESS.

The development, manufacture and commercialization of pharmaceutical products is generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal U.S. regulatory authority over pharmaceutical products, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the Federal Food, Drug, and Cosmetic Act, or FFDCA, as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the U.S. without the prior approval of the FDA or pursuant to an applicable exemption from the FFDCA. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit an NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug. Such clinical trials are required to meet good clinical practices under the FFDCA. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2). We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and NDA submission, generally takes two to three years under the 505(b)(2) NDA process. Our determinations may prove to be inaccurate or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all. The failure by us to obtain necessary regulatory approvals, whether on a timely basis or at all, would have a material adverse effect on our business. The filing of an NDA with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted.

THE CLINICAL TRIAL AND REGULATORY APPROVAL PROCESS FOR OUR PRODUCTS IS EXPENSIVE AND TIME CONSUMING, AND THE OUTCOME IS UNCERTAIN.

In order to sell our proposed products, we must receive separate regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process for an NDA includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and effectiveness and confirmation by the FDA and comparable agencies in foreign countries that the manufacturer maintains good

laboratory and manufacturing practices during testing and manufacturing. Clinical trials generally take two to five years or more to complete. Even if favorable testing data is generated by clinical trials of drug products, the FDA may not accept an NDA submitted by a pharmaceutical or biotechnology company for such drug product for filing, or if accepted for filing, may not approve such NDA.

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may fail to reach agreement with the FDA and/or comparable foreign agencies on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval.

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Delays and terminations of the clinical trials we conduct could result from insufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, stringent enrollment criteria, the proximity of the patients to the trial sites, having to compete with other clinical trials for eligible patients, geographical and geopolitical considerations and others. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects.

The FDA and comparable foreign agencies may withdraw any approvals we obtain. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the U.S., we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. Other than the approval of NitroMist™ and ZolpiMist™, the FDA and foreign regulators have not yet approved any of our products under development for marketing in the U.S. or elsewhere. If the FDA and other regulators do not approve any one or more of our products under development, we will not be able to market such products.

WE EXPECT TO FACE UNCERTAINTY OVER REIMBURSEMENT AND HEALTHCARE REFORM.

In both the U.S. and other countries, sales of our products will depend in part upon the availability of reimbursement from third-party payers, which include government health administration authorities, managed care providers and private health insurers. Third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services.

LEGISLATIVE OR REGULATORY REFORM OF THE HEALTHCARE SYSTEM MAY AFFECT OUR ABILITY TO SELL OUR CURRENT AND FUTURE PRODUCTS PROFITABLY.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our current and future products profitably. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), which includes a number of health care reform provisions and requires most U.S. citizens to have health insurance. Effective January 1, 2010, the new law increases the minimum Medicaid drug rebates for pharmaceutical companies, expands the 340B drug discount program, and makes changes to affect the Medicare Part D coverage gap, or “donut hole.” The law also revises the definition of “average manufacturer price” for reporting purposes (effective October 1, 2011), which could increase the amount of the Company’s Medicaid drug rebates to states, once the provision is effective. The new law also imposes a significant annual fee on companies that manufacture or import branded prescription drug products (beginning in 2010). Substantial new provisions affecting compliance also have been added, which may require modification of business practices with health care practitioners.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional change could be made to governmental healthcare programs that could significantly impact the success of our current and future products, and we could be adversely affected by current and future health care reforms.

OUR STRATEGY INCLUDES ENTERING INTO COLLABORATION AGREEMENTS WITH THIRD PARTIES FOR CERTAIN OF OUR PRODUCT CANDIDATES AND WE MAY REQUIRE ADDITIONAL COLLABORATION AGREEMENTS. IF WE FAIL TO ENTER INTO THESE AGREEMENTS OR IF WE OR THE THIRD PARTIES DO NOT PERFORM UNDER SUCH AGREEMENTS, IT COULD IMPAIR OUR ABILITY TO COMMERCIALIZE OUR PROPOSED PRODUCTS.

Our strategy for the completion of the required development and clinical testing of certain of our product candidates and for the manufacturing, marketing and commercialization of such product candidates includes entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute the products.

Through December 31, 2008, we entered into strategic license agreements with: (i) Hana Biosciences, for the development and marketing rights in the U.S. and Canada for our ondansetron oral spray, (ii) Par, for the marketing rights in the U.S. and Canada for NitroMist™, (iii) Manhattan Pharmaceuticals, in connection with propofol, (iv) Velcera, in connection with veterinary applications for currently marketed veterinary drugs and (v) BioAlliance Pharma SA, for the European rights for Ondansetron oral spray. Subsequent to December 31, 2008, the following events occurred with respect our strategic license agreements:

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On October 27, 2009, we entered into a license and distribution agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize the NitroMist™ lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris, in the United States, Canada and Mexico. Under the terms of the agreement, we received a $1,000,000 licensing fee upon execution of the agreement, and will receive milestone payments totaling an additional $1,000,000 over the next twelve months and ongoing performance payments of up to seventeen percent (17%) of net sales subject to potential reduction, subject to the terms of the agreement.

On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture the Company's ZolpiMist™ in the United States and Canada. ZolpiMist™ is our oral spray formulation of zolpidem tartrate, which was approved by the FDA in December of 2008. Under the terms of the agreement, ECR paid us $3,000,000 upon the execution of the agreement and will pay ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products, subject to the terms of the agreement.

Our success depends upon obtaining additional collaboration partners and maintaining our relationships with our current partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize proposed products. We may, in the future, grant to collaboration partners, rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners could limit our flexibility in considering alternatives for the commercialization of such product candidates. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize such product candidates, it may delay or prevent us from developing or commercializing our proposed products in a competitive and timely manner and would have a material adverse effect on our business.

IF WE CANNOT PROTECT OUR INTELLECTUAL PROPERTY, OTHER COMPANIES COULD USE OUR TECHNOLOGY IN COMPETITIVE PRODUCTS. IF WE INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS, OTHER COMPANIES COULD PREVENT US FROM DEVELOPING OR MARKETING OUR PRODUCTS.

We seek patent protection for our technology so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to:

- defend our patents and otherwise prevent others from infringing on our proprietary rights;
- protect our trade secrets; and
- operate without infringing upon the proprietary rights of others, both in the U.S. and in other countries.

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the U.S. Patent and Trademark Office, or USPTO, has not adopted a consistent policy regarding the breadth of claims that the USPTO allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

Section 505(b)(2) of the FFDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at

least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Act permits an applicant to rely upon the FDA's findings of safety and effectiveness for an approved product. The FDA may also require companies to perform one or more additional studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or some of the label indications for which the referenced product has been approved, or a new indication sought by the Section 505(b)(2) applicant.

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To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (1) the required patent information has not been filed (paragraph I certification); (2) the listed patent has expired (paragraph II certification); (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration (paragraph III certification); or (4) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product (paragraph IV certification). If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired, and once any pediatric exclusivity expires. The Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA holder and patent owner once the NDA has been accepted for filing by the FDA. The NDA holder and patent owner may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in an infringement case that is favorable to the Section 505(b)(2) applicant. Thus, a Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the NDA holder or patent owner does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

EVEN IF WE OBTAIN PATENTS TO PROTECT OUR PRODUCTS, THOSE PATENTS MAY NOT BE SUFFICIENTLY BROAD AND OTHERS COULD COMPETE WITH US.

We, and the parties licensing technologies to us, have filed various U.S. and foreign patent applications with respect to the products and technologies under our development, and the USPTO and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Currently, we have nine patents which have been issued in the U.S. and 52 patents which have been issued outside of the U.S. Additionally, we have over 60 patents pending around the world. Our pending patent applications, those we may file in the future and those we may license from third parties, may not result in the USPTO or any foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the USPTO or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. Such patents, which include relevant foreign patents, expire on various dates. We have filed, and when possible and appropriate, will file, other patent applications with respect to our product candidates and processes in the U.S. and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risk Factors - If We Cannot Meet Requirements Under our License Agreements, We Could Lose the Rights to our Products."

INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES COULD LIMIT OUR ABILITY TO MARKET OUR PRODUCTS.

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The USPTO keeps U.S. patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

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IF WE CANNOT MEET REQUIREMENTS UNDER OUR LICENSE AGREEMENTS, WE COULD LOSE THE RIGHTS TO OUR PRODUCTS.

We depend, in part, on licensing arrangements with third parties to maintain the intellectual property rights to our products under development. These agreements may require us to make payments and/or satisfy performance obligations in order to maintain our rights under these licensing arrangements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

In addition, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

WE RELY ON CONFIDENTIALITY AGREEMENTS THAT COULD BE BREACHED AND MAY BE DIFFICULT TO ENFORCE.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our consultants, advisors and research collaborators, to the extent that they apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we will rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with our employees, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- they will breach these agreements;
- any agreements we obtain will not provide adequate remedies for this type of breach or that our trade secrets or proprietary know-how will otherwise become known or competitors will independently develop similar technology; and
- our competitors will independently discover our proprietary information and trade secrets.

WE ARE DEPENDENT ON EXISTING MANAGEMENT AND BOARD MEMBERS.

Our success is substantially dependent on the efforts and abilities of the principal members of our management team and our directors. Decisions concerning our business and our management are and will continue to be made or significantly influenced by these individuals. The loss or interruption of their continued services could have a materially adverse effect on our business operations and prospects. Although our employment agreements with members of management generally provide for severance payments that are contingent upon the applicable officer's refraining from competition with us, the loss of any of these persons' services could adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompetition provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify hire and retain additional personnel, including scientific, development and manufacturing staff.

RISKS RELATED TO OUR COMMON STOCK

BECAUSE OUR COMMON STOCK IS LISTED ON THE OVER-THE-COUNTER BULLETIN BOARD, THE LIQUIDITY OF OUR COMMON STOCK MAY BE IMPAIRED.

On December 24, 2009, we announced that our common stock began trading on the Over-the-Counter Bulletin Board, or OTCBB. Our new ticker symbol on OTCBB is NVDL.OB. We filed Form 25 on December 14, 2009, voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009.

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Because our common stock is listed on the OTCBB, the liquidity of the common stock is impaired, not only in the number of shares that are bought and sold, but also through delays in the timing of transactions, and limited coverage by security analysts and the news media. As a result, prices for shares of our common stock may be lower than might otherwise prevail if our common stock was traded on NYSE Amex LLC or another national securities exchange.

As of March 31, 2010, our net worth position was a deficit of $4,799,000 and as of December 31, 2009, our net worth position was a deficit of $4,341,000.

WE ARE INFLUENCED BY CURRENT STOCKHOLDERS, OFFICERS AND DIRECTORS.

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. As of May 1, 2010, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 45.0% of the common stock on a fully-diluted basis. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Specifically, ProQuest has the ability to exert significant influence over matters submitted to our stockholders for approval. Such positions may discourage or prevent any proposed takeover of us, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

THE MARKET PRICE OF OUR STOCK AND OUR EARNINGS MAY BE ADVERSELY AFFECTED BY MARKET VOLATILITY.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to continue to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our common stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;

- new accounting standards; and

- the occurrence of any of the risks set forth in these Risk Factors and other reports, including this prospectus and other filings filed with the Securities and Exchange Commission from time to time.

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Our common stock is currently listed for trading on the OTCBB under the symbol "NVDL.OB" and was previously traded on the NYSE Amex LLC from May 11, 2004 to December 23, 2009. During the twelve-month period ended March 31, 2010, the closing price of our common stock has ranged from $0.12 to $0.42. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the twelve-month period ended March 31, 2010, the average daily trading volume in our common stock was approximately 392,167 shares. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

BECAUSE THE AVERAGE DAILY TRADING VOLUME OF OUR COMMON STOCK IS LOW, THE ABILITY TO SELL OUR SHARES IN THE SECONDARY TRADING MARKET MAY BE LIMITED.

Because the average daily trading volume of our common stock is low, the liquidity of our common stock may be impaired. As a result, prices for shares of our common stock may be lower than might otherwise prevail if the average daily trading volume of our common stock was higher. The average daily trading volume of our common stock may be low relative to the stocks of exchange-listed companies, which could limit investors' ability to sell shares in the secondary trading market.

WE LIKELY WILL ISSUE ADDITIONAL EQUITY SECURITIES, WHICH WILL DILUTE CURRENT STOCKHOLDERS' SHARE OWNERSHIP.

We likely will issue additional equity securities to raise capital and through the exercise of options and warrants that are outstanding or may be outstanding. These additional issuances will dilute current stockholders' share ownership.

PENNY STOCK REGULATIONS MAY IMPOSE CERTAIN RESTRICTIONS ON MARKETABILITY OF OUR SECURITIES.

The SEC has adopted regulations which generally define a "penny stock" to be any equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. As a result, our common stock is subject to rules that impose additional sales practice requirements on broker dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of $1,000,000 or annual income exceeding $200,000, or $300,000 together with their spouse). For transactions covered by such rules, the broker dealer must make a special suitability determination for the purchase of such securities and have received the purchaser's written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the transaction, of a risk disclosure document mandated by the SEC relating to the penny stock market. The broker dealer must also disclose the commission payable to both the broker dealer and the registered representative, current quotations for the securities and, if the broker dealer is the sole market maker, the broker dealer must disclose this fact and the broker dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Broker-dealers must wait two business days after providing buyers with disclosure materials regarding a security before effecting a transaction in such security. Consequently, the "penny stock" rules restrict the ability of broker dealers to sell our securities and affect the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

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Stockholders should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

- control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;
- manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;
- "boiler room" practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

Our management is aware of the abuses that have occurred historically in the penny stock market.

ADDITIONAL AUTHORIZED SHARES OF OUR COMMON STOCK AND PREFERRED STOCK AVAILABLE FOR ISSUANCE MAY ADVERSELY AFFECT THE MARKET.

We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. As of May 1, 2010, there were 98,383,000 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. As of May 1, 2010, we had outstanding stock options and warrants to purchase approximately 32.2 million shares of common stock, the exercise prices of which range between $0.17 per share and $3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof.

On July 16, 2009, we received approval from the NYSE Amex LLC to issue up to 12,000,000 shares over the next twelve (12) months. We have entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP will purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than or equal to the stated floor price of $0.25 per share. We have received $1,055,000 in gross proceeds for the closings that have occurred through December 31, 2009. As of March 24, 2010, we have received $200,140 in gross proceeds for 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP as of such date.

The following table provides an overview of our stock options and corresponding plans, as of May 1, 2010:

Plan	Shares Authorized	Options Outstanding at May 1, 2010	Remaining Shares Available for Issuance	Comments
1992 Stock Option Plan	500,000	40,000	—	Plan Closed
1997 Stock Option Plan	500,000	50,000	—	Plan Closed

1998 Stock Option Plan	3,400,000	3,045,000	60,000	—
2006 Equity Incentive Plan	6,000,000	4,354,000	1,081,000	—
Non-Plan	n/a	581,000		—
Total	10,400,000	8,070, 000	1,141,000	

As of May 1, 2010, there are 3,045,000 and 4,354,000 options outstanding under the 1998 Stock Option Plan and the 2006 Equity Incentive Plan, respectively. As a result, as of May 1, 2010, 60,000 and 1,081,000 shares remain available for issuance under the 1998 Stock Option Plan and the 2006 Equity Incentive Plan, respectively.

To the extent such options or warrants are exercised, the holders of our common stock will experience further dilution.

In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution.

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See “Risk Factors - Our Additional Financing Requirements Could Result In DilutionTo Existing Stockholders” included herein. The exercise of the outstanding derivative securities will reduce the percentage of common stock held by our stockholders in relation to our aggregate outstanding capital stock. Further, the terms on which we could obtain additional capital during the life of the derivative securities may be adversely affected, and it should be expected that the holders of the derivative securities would exercise them at a time when we would be able to obtain equity capital on terms more favorable than those provided for by such derivative securities. As a result, any issuance of additional shares of our common stock may cause our current stockholders to suffer significant dilution which may adversely affect the market.

In addition to the above referenced shares of our common stock which may be issued without stockholder approval, we have 1,000,000 shares of authorized preferred stock, the terms of which may be fixed by our Board. We presently have no issued and outstanding shares of preferred stock and while we have no present plans to issue any shares of preferred stock, our Board has the authority, without stockholder approval, to create and issue one or more series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of our common stock.

SHARES ELIGIBLE FOR FUTURE SALE MAY ADVERSELY AFFECT THE MARKET.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of our common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a six-month holding period may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by our stockholders that are non-affiliates that have satisfied a one-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

LIMITATION ON DIRECTOR/OFFICER LIABILITY.

As permitted by Delaware law, our certificate of incorporation limits the liability of our directors for monetary damages for breach of a director’s fiduciary duty except for liability in certain instances. As a result of our charter provision and Delaware law, stockholders may have limited rights to recover against directors for breach of fiduciary duty. In addition, our certificate of incorporation provides that we shall indemnify our directors and officers to the fullest extent permitted by law.

WE HAVE NO HISTORY OF PAYING DIVIDENDS ON OUR COMMON STOCK.

We have never paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We plan to retain any future earnings to finance growth. If we decide to pay dividends to the holders of our common stock, such dividends may not be paid on a timely basis.

PROVISIONS OF OUR CERTIFICATE OF INCORPORATION AND DELAWARE LAW COULD DETER A CHANGE OF OUR MANAGEMENT WHICH COULD DISCOURAGE OR DELAY OFFERS TO ACQUIRE US.

Provisions of our certificate of incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our

certificate of incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board also has the authority to issue preferred stock without further stockholder approval, including large blocks of preferred stock. As a result, our Board could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of our common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock.

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SALES OF LARGE QUANTITIES OF OUR COMMON STOCK, INCLUDING THOSE SHARES ISSUABLE IN CONNECTION WITH PRIVATE PLACEMENT TRANSACTIONS, COULD REDUCE THE PRICE OF OUR COMMON STOCK.

On March 31, 2010, we announced we would receive approximately $1.5 million in gross proceeds from our registered direct offering (the "Offering") of 9,100,001 shares of common stock, par value $0.001 per share (the "Common Shares"), at a price of $0.165 per share. The investors received five-year warrants (the "Series A Warrants") to purchase 4,550,001 shares of common stock with an exercise price of $0.25 per share and six-month warrants (the "Series B Warrants," together with the Common Shares and the Series A Warrants, the "Securities") to purchase 3,033,334 shares of common stock at an exercise price of $0.25 per share. As of March 31, 2010, we recorded net proceeds of $551,000 and a note receivable of $800,000 which was subsequently received on April 15, 2010, relating to the Offering. The exercise price of the Series A and Series B Warrants are subject to adjustment as provided by such warrants. The Offering closed on March 31, 2010 and we sold the Securities pursuant to an effective registration statement.

On July 16, 2009, we received approval from the NYSE Amex LLC to issue up to 12,000,000 shares over the next twelve (12) months. We have entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP will purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than or equal to the stated floor price of $0.25 per share. The Company received net proceeds of $1,183,000 thru March 31, 2010 of which $191,100 was received for the three months ended March 31, 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP.

In October 2008, we sold securities in the subsequent closing of the 2008 Financing, resulting in the issuance of notes convertible into 10,744,681 shares of our common stock, and warrants to purchase 6,446,809 shares of our common stock. The sale of the notes and warrants resulted in gross proceeds to us of $2,525,000, before deducting certain fees and expenses.

In May 2008, we sold securities in the initial closing of the 2008 Financing, resulting in the issuance of notes convertible into 5,000,000 shares of our common stock, and warrants to purchase 3,000,000 shares of our common stock. The sale of the notes and warrants resulted in gross proceeds to us of $1,475,000, before deducting certain fees and expenses.

In December 2006, we sold securities in a private placement transaction resulting in the issuance of 9,823,983 shares of our common stock, and warrants to purchase 4,383,952 shares of our common stock. The sale of the shares of common stock and warrants resulted in gross proceeds to us of approximately $14.2 million, prior to offering expenses.

On July 20, 2006, we filed a shelf registration statement on Form S-3 registering for sale by us of up to 14,000,000 shares of our common stock. Such shelf registration statement was declared effective by the SEC on August 2, 2006. We may offer and sell such shares from time to time, in one or more offerings in amounts and at prices, and on terms determined at the time of the offering. Such offerings of our common stock may be made through agents we select or through underwriters and dealers we select. If we use agents, underwriters or dealers, we will name them and describe their compensation at the time of the offering. As of the filing date of this prospectus, such shelf registration statement is no longer effective.

In April 2006, we sold securities in a private placement transaction resulting in the issuance of 8,092,796 shares of our common stock, and warrants to purchase 2,896,168 shares of our common stock. The sale of the shares of common stock and warrants resulted in gross proceeds to us of approximately $11.8 million, prior to offering expenses.

In May 2005, we sold securities in a private placement transaction resulting in the issuance of 6,733,024 shares of our common stock, and certain warrants to purchase 2,693,210 shares of our common stock. The sales of the shares of common stock and warrants resulted in gross proceeds to us of approximately $7.1 million, prior to offering expenses.

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The offering of, and/or resale of our common stock and the exercise of the warrants described immediately above in this risk factor are subject to currently effective registration statements filed by us on Forms S-3. There can be no assurance as to the prices at which our common stock will trade in the future, although they may continue to fluctuate significantly. Prices for our common stock will be determined in the marketplace and may be influenced by many factors, including the following:

- The depth and liquidity of the markets for our common stock;
- Investor perception of us and the industry in which we participate; and
- General economic and market conditions.

Any sales of large quantities of our common stock could reduce the price of our common stock. The holders of the shares may sell such shares at any price and at any time, as determined by such holders in their sole discretion without limitation. If any such holders sell such shares in large quantities, our common stock price may decrease and the public market for our common stock may otherwise be adversely affected because of the additional shares available in the market.

As of May 1, 2010, we have 98,383,000 shares of common stock issued and outstanding and approximately 28.1 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In the event we wish to offer and sell shares of our common stock in excess of the 200,000,000 shares of common stock currently authorized by our certificate of incorporation, we will first need to receive stockholder approval. Such stockholder approval has the potential to adversely affect the timing of any potential transactions.

THE SECURITIES ISSUED IN OUR PRIVATE PLACEMENTS ARE RESTRICTED SECURITIES.

At the time of the offer and sale of the common stock and the shares of common stock underlying the convertible notes and the warrants, as applicable, in our December 2006 private placement and 2008 private placement, the common stock was not registered under the Securities Act or the securities laws of any state. Accordingly, these securities may not be sold or otherwise transferred unless such sale or transfer is subsequently registered under the Securities Act and applicable state securities laws or unless exemptions from such registration are available. The registration statements covering the December 2006 private placement and the 2008 private placement were declared effective by the SEC on January 26, 2007, and July 16, 2008 and May 5, 2009, respectively. Notwithstanding our registration obligations regarding these securities, investors may be required to hold these securities for an indefinite period of time. All investors who purchase these securities are required to make representations that it will not sell, transfer, pledge or otherwise dispose of any of the securities in the absence of an effective registration statement covering such transaction under the Securities Act and applicable state securities laws, or the receipt by us of an opinion of counsel to the effect that registration is not required.

WE HAVE BROAD DISCRETION AS TO THE USE OF THE PROCEEDS FROM OUR FINANCINGS AND MAY USE THE PROCEEDS IN A MANNER WITH WHICH YOU DISAGREE.

Our Board and management has broad discretion over the use of the net proceeds from our past financings, and will have broad discretion over the use of the net proceeds from any future financings. Stockholders may disagree with the judgment of the Board and management regarding the application of the proceeds. We cannot predict that investments of the proceeds will yield a favorable, or any, return.

WE MAY INCUR SIGNIFICANT COSTS FROM CLASS ACTION LITIGATION DUE TO OUR EXPECTED STOCK VOLATILITY.

In the past, following periods of large price declines in the public market price of a company's stock, holders of that stock occasionally have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring this type of lawsuit against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit also could divert the time and attention of our management, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

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THE UNCERTAINTY CREATED BY CURRENT ECONOMIC CONDITIONS AND POSSIBLE TERRORIST ATTACKS AND MILITARY RESPONSES THERETO COULD MATERIALLY ADVERSELY AFFECT OUR ABILITY TO SELL OUR PRODUCTS, AND PROCURE NEEDED FINANCING.

Current conditions in the domestic and global economies continue to present challenges. We expect that the future direction of the overall domestic and global economies will have a significant impact on our overall performance. Fiscal, monetary and regulatory policies worldwide will continue to influence the business climate in which we operate. If these actions are not successful in spurring continued economic growth, we expect that our business will be negatively impacted, as customers will be less likely to buy our products, if and when we commercialize our products. In addition, the potential for future terrorist attacks or war as a result thereof has created worldwide uncertainties that make it very difficult to estimate how the world economy will perform going forward.

OUR INABILITY TO MANAGE THE FUTURE GROWTH THAT WE ARE ATTEMPTING TO ACHIEVE COULD SEVERELY HARM OUR BUSINESS.

We believe that, given the right business opportunities, we may expand our operations rapidly and significantly. If rapid growth were to occur, it could place a significant strain on our management, operational and financial resources. To manage any significant growth of our operations, we will be required to undertake the following successfully:

- We will need to improve our operational and financial systems, procedures and controls to support our expected growth and any inability to do so will adversely impact our ability to grow our business. Our current and planned systems, procedures and controls may not be adequate to support our future operations and expected growth. Delays or problems associated with any improvement or expansion of our operational systems and controls could adversely impact our relationships with customers and harm our reputation and brand.

- We will need to attract and retain qualified personnel, and any failure to do so may impair our ability to offer new products or grow our business. Our success will depend on our ability to attract, retain and motivate managerial, technical, marketing, and administrative personnel. Competition for such employees is intense, and we may be unable to successfully attract, integrate or retain sufficiently qualified personnel.

If we are unable to hire, train, retain or manage the necessary personnel, we may be unable to successfully introduce new products or otherwise implement our business strategy. If we are unable to manage growth effectively, our business, results of operations and financial condition could be materially adversely affected.

WE MAY BE OBLIGATED, UNDER CERTAIN CIRCUMSTANCES, TO PAY LIQUIDATED DAMAGES TO HOLDERS OF OUR COMMON STOCK.

We have entered into agreements with the holders of our common stock that requires us to continuously maintain as effective, a registration statement covering the underlying shares of common stock. Such registration statements were declared effective on January 26, 2007, May 30, 2006 and July 28, 2005 and must continuously remain effective for a specified term. If we fail to continuously maintain such a registration statement as effective throughout the specified term, we may be subject to liability to pay liquidated damages.

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ITEM 6. EXHIBITS

INDEX TO EXHIBITS

The following exhibits are included with this Quarterly Report. All management contracts or compensatory plans or arrangements are marked with an asterisk.

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
1.1	Placement Agent Agreement, dated as of March 31, 2010, between NovaDel Pharma Inc. and Chardan Markets, LLC as placement agent.	Incorporated by reference to Exhibit 1.1 of the Company's Current Report on Form 8-K filed on March 31, 2010.
4.1	Form of Series A Warrants.	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 31, 2010.
4.2	Form of Series B Warrants.	Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on March 31, 2010.
10.1	Securities Purchase Agreement, dated March 31, 2010, among NovaDel Pharma Inc. and the investors set forth therein.	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 31, 2010.
10.2	Termination Agreement, dated as of March 26, 2010, between NovaDel Pharma Inc. and Seaside 88, LP.	Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 31, 2010.
31.1	Certification of Chief Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32.1	Certification of the President, Chief Executive Officer and Interim Chief Financial Officer under 18 USC 1350, Section 1330 as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NovaDel Pharma Inc.

Date: May 17, 2010

By: /s/ STEVEN B. RATOFF
Steven B. Ratoff
President, Chief Executive Officer and Interim Chief Financial Officer
(principal executive officer)
(principal financial officer)